HANDBOOK FOR INVESTIGATORS:

For the Protection of Human Subjects in Research

INSTITUTIONAL REVIEW BOARD
125 Coble Hall
University of Illinois at Urbana-Champaign
September 1983

Emergencies

McKinley Health Center is available for emergencies which may arise during the course of research involving human subjects.

In an emergency, do as follows:

1. Call 333-2700:
   - State the location and nature of the emergency,
   - State the relationship of the emergency to the research, *and*
   - Give the principal investigator's name and phone number.
2. Report the event promptly to:
   - Your Departmental Executive Officer *and*
   - The Institutional Review Board, 333-2670.

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Summary Guide for Investigators

Who must follow the UIUC policy and procedures?

Any individual who is responsible for a research activity involving human subjects *conducted at* or *sponsored by* the University of Illinois.

Who may conduct research involving human subjects?

Any research involving human subjects must have associated with it a Responsible Project Investigator who is a qualified faculty member at or above the level of instructor, or a qualified staff member, and who will monitor the conduct of the research.

To what activities do the UIUC policy and procedures apply?

To any research activity which involves human subjects, whether such research is undertaken on a large or small scale, whether it is preliminary or fully designed, whether it is student or faculty research, whether it is externally funded or not, and whether it involves minimal risk or more than minimal risk. (See Part II, Section A, page 5.)

What is meant by the terms *human subject, research, minimal risk, informed consent?*

See Part II, Sections C and D, pages 8-20.

What are the requirements for informed consent?

The voluntary informed consent of subjects is a basic ethical principle essential to the conduct of all research with humans whether or not the research is governed by federal regulations and whether or not the research is subject to prior review.

The requirements regarding methods used to obtain consent and documentation of the consent process vary according to the nature of the project and its sponsorship. (See Part II, Section D, pages 12-20.)

What kinds of research require review?

All research involving human subjects must be submitted for review *unless the only involvement of human subjects will comply fully with the criteria for one or more of the exemption categories* set forth in Part III, Section A, pages 28-34.

What is the purpose of the review?

To obtain an independent determination of whether the research meets the criteria for approval set by UIUC and certain sponsoring agencies. (See Tables 6A and 6B, pages 41-44.)

When must a nonexempt research activity involving human subjects be reviewed?

Prior to the initiation of activity (unless the research is necessary to eliminate apparent immediate hazards to the human subject), *prior to* the implementation of changes in previously approved procedures involving human subjects, and *at least annually* during the lifetime of the project. If the project is being proposed for external funding, review should take place *prior to* or *shortly after* submission of a proposal to the sponsor. (See Part III, Section C, pages 38-39.)

Who will perform the review?

The locus of the review depends on the nature of the activity and the source of funding. (See Table 5, Part III, page 36.)

What is the review process?

See Figure 1, Part III, page 37.

What must be submitted for review?

Form IRB-1 (or a department's substitute therefor) providing sufficient information for the Institutional Review Board (IRB) or IRB-approved departmental review body to make a fair and reasonable judgment as to the project's compliance with all requirements. (See Part III, Section F, pages 40, 44, and 45, for greater detail.)

How will the principal investigator find out the result of the review?

Via written notification from the review body.

How can an investigator obtain information or advice regarding use of human subjects?

Contact the Executive Secretary of the Institutional Review Board (333-2670) who will either provide the information or arrange for consultation with one or more members of the IRB.

Are there special requirements if certain kinds of subjects, such as children, pregnant women, or prisoners are included in the research?

Yes. See Appendix IV, pages 67-74.

Are there special requirements if access to subjects is gained through cooperating institutions not under UIUC control?

Yes. See Part III, Section F2*e* and *k*, pages 44 and 45.

Are there special requirements if plans for use of human subjects are indefinite or arise during the course of a project in which no use of subjects was planned?

Yes. See Part III, Section C, pages 38-39.

How should emergencies involving human subjects be handled?

Contact McKinley Health Center (333-2700). State the location and the nature of the emergency. Inform McKinley personnel of the relationship of the emergency to the research activity; give the principal investigator's name and telephone number.

Promptly report any such event to the Departmental Executive Officer *and* the Institutional Review Board (333-2670).

What are the subjects' responsibilities and privileges?

Subjects are free to ask questions and withdraw from participation at any time. They may have access to a copy of the UIUC policy and procedures.

Subjects may take unresolved complaints or concerns to the Departmental Executive Officer and, if the matter remains unresolved, to the Executive Secretary of the Institutional Review Board.

Subjects are expected to notify the investigator promptly if adverse effects of participation are experienced.

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Part I: Ethical and Professional Standards for Use of Human Subjects in Research

The use of human subjects in research can be extremely important to the development of new knowledge in many areas. Ultimately, the only sure means for learning specifically about man is through studying man himself. Responsible investigation involving human beings as subjects, however, demands that careful attention be given to questions of ethics and human dignity. During the War Crimes Trials following World War II, the Nuremberg Code[1] was drafted as a set of standards for judging physicians and scientists who had conducted biomedical experiments on concentration camp prisoners. This code has been widely adopted by investigators conducting studies on human beings and has served as the prototype of many later codes intended to ensure that research involving human subjects would be carried out in an ethical manner.

Since 1947, various codes for the proper and responsible conduct of research involving human subjects have been developed by professional associations to guide investigators working in the various disciplines involved. Over the years, experience has shown that while these codes have been helpful, they are frequently difficult to interpret or to apply, particularly in nonmedical research projects which involve human subjects. As part of its work, the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research developed broader ethical principles to provide a basis on which specific rules could be formulated, criticized and interpreted. These principles are discussed in *The Belmont Report.*[2]

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[1] *Trials of War Criminals Before the Nuremberg Military Tribunals.* Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. (1947).

[2] *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research.* The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, DHEW Publication No. (OS) 78-0012 (1978).

The Belmont Principles and the Nuremberg Code are stated below. Appendix I of this document gives a listing of the various ethical codes developed by professional associations and the addresses from which copies may be obtained. The Office of the Executive Secretary of the Institutional Review Board, 125 Coble Hall, and the University Library have copies of these ethical codes available for review.

A. The Belmont Principles

Three basic principles, among those generally accepted in our cultural tradition, are particularly relevant to the ethics of research involving human subjects: *respect for persons, beneficence,* and *justice.*

1. Respect for Persons

Respect for persons incorporates at least two basic ethical tenets: first, that individuals should be treated as autonomous agents and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement *to acknowledge autonomy* and the requirement *to protect those with diminished autonomy.*

To respect autonomy is to give weight to autonomous persons' considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others. Respect for the immature and the incapacitated may require protecting them as they mature or while they are incapacitated.

In most cases of research involving human subjects, respect for persons demands that subjects enter the research voluntarily and on the basis of adequate information about the research situation and possible consequences.

2. Beneficence

Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Such treatment falls under the principle of beneficence. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) *do not harm* and (2) *maximize possible benefits and minimize possible harms.* Learning what will, in fact, benefit may require exposing persons to risk. The problem posed by these imperatives is to decide when it is justifiable to seek certain benefits, despite the risks involved, and when the possible benefits should be foregone because of the risks.

The obligations of beneficence affect both individual investigators and society at large, because they extend both to particular research projects and to the entire enterprise of research. In the case of par-

ticular projects, investigators and members of their institutions are obliged to give forethought to the maximization of benefits and the reduction of risks that might occur from the research investigation. In the case of scientific research in general, members of the larger society are obliged to recognize the longer term benefits and risks that may result from the improvement of knowledge and from the development of novel medical, psychotherapeutic, and social procedures.

3. Justice

Who ought to receive the benefits of research and bear its burdens? This is a question of justice — in the sense of "fairness in distribution" or "what is deserved." An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly. The selection of research subjects needs to be scrutinized in order to determine whether some groups (e.g., welfare patients, particular racial and ethnic minorities, or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied. Especially when research supported by public funds leads to the development of therapeutic devices and procedures, justice demands that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research.

B. The Nuremberg Code

1. The voluntary consent of the human subject is absolutely essential.
2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of disease or other problem under study that the anticipated results will justify the performance of the experiment.
4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
5. No experiment should be conducted where there is an *a priori* reason to believe that death or disabling injury will occur — except perhaps in those experiments where experimental physicians also serve as subjects.
6. The degree of risk to be taken should never exceed that determined

by the humanitarian importance of the problem to be solved by the experiment.

7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.

8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

9. During the course of the experiment, the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.

10. During the course of the experiment, the scientist in charge must be prepared to terminate the experiment at any stage if he has probable cause to believe, in the exercise of good faith, superior skill, and careful judgment required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

Part II: UIUC Policy for Use of Human Subjects in Research

A. Applicability

This policy is applicable to any research activity conducted at or sponsored by the University of Illinois at Urbana-Champaign which involves human subjects, i.e., living individuals about whom an investigator (professional or student) conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information. The policy is therefore applicable to research involving human beings whose physical, emotional, or behavioral condition, responses, tissues, or fluids are investigated for any purpose other than for the sole purpose of benefiting the subject as an individual. It is applicable to the use of interviews, tests, observations, and inquiries designed to elicit or obtain nonpublic information about individuals or groups.

The policy is applicable whether the research is undertaken on a large or small scale. Pilot projects, student dissertation projects, independent study projects, and course projects must follow this policy if they involve human subjects in research.

B. Statement of Policy

The University of Illinois at Urbana-Champaign affirms the need for academic freedom in the conduct of research and the value of well-designed, responsible activities which involve human subjects. At the same time, it recognizes its basic responsibility to assure the protection of any human subjects so involved. To this end, it has adopted the following statement of policy:

1. Investigations conducted at or sponsored by the University of Illinois at Urbana-Champaign must:
   a. adhere to the Belmont Principles, and
   b. comply with the Nuremberg Code or one of the ethical codes developed by the various professional associations, and
   c. adhere to the policies and procedures set forth in this document.
2. Participation of human beings as subjects in research governed by this policy must be *voluntary,* i.e., it must occur as the result of free choice, without compulsion or obligation.

   Both the rights of such individuals to be protected against injury or invasions of their privacy and their interests as members of a free

society in preserving their dignity are recognized as major concerns and must be protected. Therefore, research involving human subjects should be undertaken only with the voluntary consent of the subject or, if the subject lacks the capacity to consent, with the consent of his or her authorized representative.

Where minors, mentally retarded, or mentally disabled persons, individuals with limited civil freedom, pregnant women, fetuses, or children are subjects in research, special care must be taken to assure that consent for participation is obtained in accordance with applicable statutes and regulations. The consent of authorized representatives is usually required for subjects who have diminished capacity to consent. The assent of the subjects themselves is usually required as well as the consent of their representatives.

3. Adequate standards for informed consent must be satisfied.

In addition to *voluntariness* as described above, *disclosure* and *comprehension* are essential elements of the consent process.

Disclosure generally includes: the research procedures; their purposes, risks, and anticipated benefits; alternative procedures where therapy is involved; and a statement offering the subject the opportunity to ask questions and to withdraw at any time from the research. The extent and nature of information should be such that persons, knowing that the procedures are neither necessary for their care nor perhaps fully understood, can decide whether they wish to participate in the furthering of knowledge. Even when some direct benefit to them is anticipated, subjects should understand clearly the range of risk and the voluntary nature of participation.

In some research, fully informing the subject would invalidate the research. In such cases, it may be necessary to withhold information from the subject. However, information should not be withheld if withholding it would affect a reasonable person's decision to participate or damage his or her subsequent self-esteem. Information about risks should never be withheld for the purpose of eliciting the cooperation of subjects, and truthful answers should always be given to direct questions about the research.

Incomplete disclosure is only justified if it is clear that:

a. incomplete disclosure is truly necessary to accomplish the goals of the research,

b. there are no undisclosed risks to subjects that are more than minimal, and

c. where appropriate, there is an adequate plan for debriefing subjects and disseminating research results to them.

Care should be taken to distinguish cases in which disclosure would destroy or invalidate the research from cases in which disclosure would simply inconvenience the investigator.

Comprehension is the third essential element in informed consent. The manner and context in which information is conveyed is as important as the information itself. Consideration must be given to the subject's ability to understand the language and terminology used as well as the subject's physical and mental state. Investigators are responsible for ascertaining that the subject has comprehended the information.

Additional details regarding the consent process and certain requirements for documentation of consent are given in Section D1, UIUC standards for consent, pages 12-20.

4. Adequate provision must be made to protect the privacy of subjects and to maintain the confidentiality of identifiable information.

Confidentiality provisions must meet reasonable standards for protection of privacy and comply with applicable laws. Identifiable information must not be disclosed outside the research group unless the subjects expressly agree otherwise.

5. The selection of subjects must be carefully considered.

The principle of *justice* gives rise to moral requirements that there be fair procedures and outcomes in the selection of research subjects. For example, *individual justice* dictates that subjects should not be selected for potentially beneficial research on the basis of favoritism. Nor should risky research be restricted to subjects who are powerless. *Social justice* requires recognition of differences among groups in the ability to bear burdens; gives an order of preference in the selection of types of subjects (for example, adults before children) ; and dictates that some types of persons (for example, institutionalized mentally infirm or prisoners) may be involved as research subjects only on certain conditions.

Certain groups, such as racial minorities, the economically disadvantaged, the very sick, and the institutionalized, may continually be valuable as research subjects owing to their ready availability in settings where research is conducted. Given their dependent status and their frequently compromised capacity for free consent, they should be protected against the danger of being involved in research solely for administrative convenience or because they are easy to manipulate as a result of their illness or socioeconomic condition.

6. The methods used for approaching subjects and securing their participation should be designed carefully to protect the privacy of the

subjects and should be reasonable in terms of their condition or circumstances.

No coercion, explicit or implicit, should be used to obtain or maintain cooperation. Where the professional-client or faculty-student relationship is converted into an investigator-subject relationship, special care must be taken to assure that the subject feels completely free to decline to participate. Where access to subjects is gained through cooperating institutions or individuals, care should be taken not to abridge prior commitments made to the subjects about the confidentiality or other terms of the primary relationship.

7. Any payment made to subjects should not be large enough to constitute excessive inducement for participation of the subjects.

8. Projects involving human subjects should be carefully designed to minimize risk to the subjects.

As far as possible, any risk should be anticipated in advance. Proper precaution should be taken and plans made to deal with emergencies that may develop in the course of even seemingly routine activities.

9. Except for certain kinds of research, described in Section A of Part III, all research involving human subjects conducted at or sponsored by the University of Illinois at Urbana-Champaign must be submitted for *prior* review and timely periodic review after approval, in accordance with the policies and procedures of the Institutional Review Board. Furthermore, changes in approved research may not be initiated without prior review.

C. Definition of Terms

1. Research

Human beings may be studied in many ways and under a vast variety of circumstances and conditions. For these reasons, the word *research* is elusive and difficult to define with precision. On the one hand, *research* may be used to describe something as innocuous as a new approach to teaching or the questions in a public opinion survey. On the other hand, *research* may refer to procedures in which the subject may be exposed to the gravest mortal risks, such as the astronaut who prepares to be launched into space to orbit the earth or journey to the moon.

As used in this document, the word *research* is defined as a trial or special observation, usually made under conditions determined by the investigator, which aims to test a hypothesis, to discover some unknown principle or effect, or to re-examine some known or suggested truth. The term *research* is intended to apply to systematic studies in

which any substance or stimulus is administered to a subject by any route. It is intended to apply to studies which involve changes in physical or psychological state or environment or major changes in diet and to the pertinent methods for studying alterations in body functions and behavior under such conditions. It is intended to apply to the use of interviews, tests, observations, and inquiries designed to elicit or obtain nonpublic information about individuals or groups.

Activities which meet this definition constitute *research* whether or not they are supported or funded under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

The term *research* is *not* intended to apply to routine course development, including evaluation of the effectiveness of such development, of courses sponsored by the University of Illinois.

2. Human Subject

The term *human subject* means a living individual about whom an investigator (professional or student) conducting research obtains

- data through intervention or interaction with the individual, or
- identifiable private information.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subjects' environment that are performed for research purposes. *Interaction* includes communication or interpersonal contact between investigator and subject. *Private information* includes information about behavior that occurs in contexts in which an individual can reasonably expect that no observation or recording is taking place and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Information is *individually identifiable* if the identity of the subject is, or may be, readily ascertained by the investigator or associated with the information.

The definition of *subject* excludes all accepted and established service relationships, such as the normal relationship of patients to physicians, students to professors, and other clients to professionals in which the patient, student, or client is receiving aid or services consistent with accepted and established practice, and intended *only to meet his or her own personal needs.* The professional-client relationship has the welfare of the client as the primary objective, whereas the investigator-subject relationship has the discovery of new knowledge as its primary objective. This difference may not be fully understood by the subject

who is also a client, and can result in the investigator's gaining consent without free decision — in part due to a trust based on a presumed role which the investigator is not necessarily fulfilling at that time.

The normal employer-employee relationship, in which legitimate services are rendered for salary, wages, or remuneration in keeping with customary written or verbal contracts, is also excluded from the definition of subject. Payment of subjects does not alter their status as subjects.

If doubt exists as to whether the procedures to be employed are within accepted and established practice or whether the purpose is only for the personal needs of the client, the activity should be considered to involve subjects whose rights and welfare are to be protected in accord with this policy statement. Similarly, if doubt exists as to whether the procedures are within the normal limits of the employee's work scope, employees should be considered to be participating as human subjects, and their rights and welfare must be protected.

a. Types of Subjects

There are several types of human subjects. For example, the subject may be an adult, a minor, a student, a hospitalized patient, a client, a resident of an institution for the mentally ill or retarded, a prison inmate, etc. Informants, and donors of organs, tissues, body fluids, and of services are also considered to be subjects. (Such donors are subjects *only* if what they provide is used for research purposes.)

Of particular concern are the following types of subjects:

i. Children, including the newborn and minors, because of their vulnerability, diminished autonomy, and incomplete understanding;

ii. Subjects with limited civil freedom, such as prisoners, residents or clients of institutions for the mentally ill and mentally retarded, and persons subject to military discipline; and

iii. Pregnant women and the viable fetus, both *in utero* and *ex utero*. (The unborn should be considered subjects to the extent that they have rights that can be exercised by their next of kin or legally authorized representative.)

3. Minimal Risk

Minimal risk means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Certain risks are inherent in life itself, at the time and in the places where life runs its course. Risks of daily life include the ordinary risks of public or private living; those risks associated with admission to a school or hospital; and the risk inherent in professional practice, as long as these do not exceed the bounds of established and accepted procedures, including innovative practices applied in the interest of the individual patient, student, or client.

The fact that some types of research do not involve risks beyond those experienced in daily life situations does not mean that the investigator is any less responsible for his or her subjects.

Section D3c provides the special safeguards required for activities involving minimal risk and activities involving greater than minimal risk. It also provides examples of types of research which fall into each of these two categories.

4. Responsible Project Investigator

Responsible project investigator means a qualified faculty member at or above the level of instructor or a qualified staff member who will monitor the conduct of research involving human subjects.

5. Children

Children means persons who have not attained the legal age for consent to treatments or procedures involved in research, under the applicable law of the jurisdiction in which the research will be conducted. (In Illinois this age is eighteen years.)

6. Legally Authorized Representative, Parent, Guardian

Legally authorized representative means an individual or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

Parent means a child's biological or adoptive parent.

Guardian means an individual who is authorized under applicable state or local laws to consent on behalf of a child to general medical care.

7. Advocate

Advocate means an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

D. UIUC Standards

1. Informed Consent

The ethical and professional codes governing the use of human subjects in research all require that the participation of the subject must be voluntary, i.e., the subject gives his or her informed consent, or his or her authorized representative consents if the subject lacks the capacity to consent.

The principle of voluntary participation of subjects applies whether or not the research is governed by federal regulations and whether or not the research is subject to prior review.

The methods used to obtain consent may vary. They should be designed to fit the nature of the research, the nature and magnitude of the risks involved, the research setting, the nature of the subjects who will participate, and the requirements of applicable policies, laws, and regulations.

a. Core Elements of Consent

The core requirements for informed consent are:

- disclosure of the nature and general purpose of the research procedures and identification of any procedures which are experimental;
- disclosure of any risks and the anticipated benefits of the research, either to the subject or to society;
- where therapy is involved, a description of alternative procedures or courses of treatment, if any, that might be advantageous to the subject; and
- provision for assuring that the subjects understand they may ask questions and/or withdraw at any time from the research.

Please note that additional elements of informed consent are required for work governed by the Department of Health and Human Services (HHS) (i.e., all work supported by HHS and other agencies which have adopted the HHS regulations). The specific elements required by HHS regulations are given in Table 1, pages 16-19.

The Institutional Review Board may approve a consent process which does not include, or which alters, any or all of the four elements of consent set forth above if it believes that the modifications are necessary, if they do not adversely affect the rights and welfare of the subjects, and if they are permitted by applicable laws and regulations.

Table 1 includes the special criteria the Institutional Review Board must follow to modify some or all of the elements of consent set forth in the HHS requirements.

b. Additional Consent Requirements

Five additional requirements regarding consent must be met:

- The consent may not include any exculpatory language through which the subject is made to waive, or appear to waive, any of his or her legal rights, including any release of the institution or its agents from liability or negligence.
- Applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective must be complied with.
- The consent requirements described herein place no limits on the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.
- When children are involved as subjects in research and are capable of assent, normally their assent to participate must be solicited in addition to the permission of their parents.
- Where participation as human subjects of students enrolled in a course of instruction at UIUC forms an integral part of the conduct of the course, the official University bulletins and timetables shall state that fact in the description of the course. A statement such as the following shall be included in the course description: "Includes limited voluntary participation as a subject in research activities."

  This statement will serve to alert registrants of this characteristic of the course, but would not suffice as the only means of assuring that the subjects' participation in a specific research activity is voluntary. Care must be exercised to assure the absence of coercion, either real or perceived, in utilizing students as subjects.

c. Consent Process

An investigator shall seek consent only under circumstances that provide the prospective subject or the subject's representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. Investigators are responsible for ascertaining that the subject or subject's representative has comprehended the information.

Occasionally, fully informed consent may itself have an injurious effect on the subject, or it may invalidate the research. Incomplete disclosure is only justified if it is clear that:

- incomplete disclosure is truly necessary to accomplish the goals of research or to protect the subjects; and
- there are no undisclosed risks to subjects that are more than minimal; and
- where appropriate, there is an adequate plan for debriefing subjects and for dissemination of research results to them.

Information shall not be withheld if withholding it would influence a reasonable person's decision to participate or damage his or her subsequent self-esteem. Information about risks shall never be withheld for the purpose of eliciting the cooperation of subjects, and truthful answers should always be given to direct questions about the research. Care shall be taken to distinguish cases in which disclosure would destroy or invalidate the research from cases in which disclosure would simply inconvenience the investigator.

In research which requires prior review, the justification for incomplete disclosure must be explicitly stated in the materials submitted for review.

The methods used to obtain consent may vary. They should be designed to fit the nature of research, the nature and magnitude of the risks involved, the research setting, and the nature of the subjects who will participate.

i. Consent Methods for Minimal Risk Research

When the research *does not place the subjects at more than minimal risk,* there is no single method required to assure that the subject consents to participation. For example, consent may be secured by a written document; it may be obtained orally; it may be implicit in voluntary participation in a well-advertised activity; or, in the case of research in commonly accepted educational settings and involving normal educational practices the consent of the appropriate educational officials may serve as a substitute for the individual subject's consent.

If, however, a written consent form is used, it should include at least the core requirements for informed consent given above and should also include the telephone number of an individual who will be available to answer inquiries from subjects. When a written consent form is used, a copy should be given to the subject. If the basic elements of consent are presented orally and only the subject's formal consent is obtained in writing, the subject should be given a copy of a written summary of the oral explanation.

For those research projects which require prior review in accordance with the IRB policies and procedures, the materials submitted for review must include a copy of the written consent form and summary of oral explanation, if any. (Examples of consent forms are provided in Appendix II.)

ii. Consent Methods for Research Involving More Than Minimal Risk

When the research *places the subjects at more than minimal risk,* the investigator is obligated to obtain legally effective informed consent, and a written consent document is usually preferred. The consent document must be approved by the Institutional Review Board. It must be signed by the subject or the subject's legally authorized representative. A copy must be given to the person signing the form. The subject or the subject's legally authorized representative must be given an opportunity to read the form before it is signed, even if the consent form is read to the subject.

The written informed consent document may either be a long-form document incorporating all the basic elements of informed consent or a short-form document which makes reference to an oral presentation of the basic elements of informed consent. If the short form is used, the Institutional Review Board must approve a written summary of what is to be said to the subject or the subject's representative. Further, there must be a witness to the oral presentation when the short form is used. Whereas the subject or his or her representative only needs to sign the short form itself, the witness and the person actually obtaining consent must sign both the short form and a copy of the summary. A copy of the summary must be given to the subject or his or her representative in addition to a copy of the short consent form. (Examples of consent forms are provided in Appendix II.)

The Institutional Review Board may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds that the only record linking the subject and the research would be the consent document and the principle risk would be potential harm resulting from a breach of confidentiality.

d. Documentation of Consent

For research which involves only minimal risk, the investigator must keep a description of the consent process used. If a written

consent document is used, the investigator must keep a copy of a sample of the consent form. The investigator is advised to retain copies of the signed consent documents themselves for three years from the date the consent was obtained. (Examples of consent forms are provided in Appendix II.)

If the research involves more than minimal risk, the investigator must retain copies of a sample of the written consent form, copies of the signed consent documents, a copy of the written summary of an oral explanation, if any, signed by the person obtaining consent and the witness to the oral explanation. These consent documents must be retained for a period of three years after the consent was obtained, unless applicable law or supporting agency requirements demand a longer retention of such records.

If the Institutional Review Board permits use of a method other than written informed consent for research involving more than minimal risk, the investigator and the Institutional Review Board should retain a copy of the description of the method used and the justification for waiving the requirement for written informed consent.

Note that work governed by the HHS regulations must comply with the documentation requirements set forth in Table 2, page 20.

(Text continues on page 21.)

TABLE 1: HHS REQUIREMENTS* FOR INFORMED CONSENT

A. Basic Elements of Informed Consent

(a) Basic elements of informed consent. Except as provided in paragraph (c) of this section, in seeking informed consent the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained. In projects regu-

* FDA requirements differ slightly: omitting A. (d) and specifying the documentation required when informed consent is waived in emergency situations.

lated by the Food and Drug Administration, subjects must be informed that there is a possibility that their records may be inspected by the FDA.

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not practicably be carried out without the waiver or alteration; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:

(i) programs under the Social Security Act, or other public benefit or service programs,

(ii) procedures for obtaining benefits or services under those programs,

(iii) possible changes in or alternatives to those programs or procedures, or

(iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) The research could not practicably be carried out without the waiver or alteration.

(e) The informed consent requirements in these regulations are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in these regulations is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

B. Consent and Assent Requirements for Research Involving Children

(a) *In addition to* the consent requirements described in A. above, the following requirements apply to research involving children:

(1) When children are subjects in research, solicitation of their assent as well as the consent of their parents or guardians is normally required. (See also Appendix IV, page 67 and Tables 6A and 6B, Criteria for IRB Approval, pages 41 and 42.)

(2) "Assent" means a child's affirmative agreement to participate in research. Mere failure to object should *not,* without affirmative agreement, be construed as assent.

(3) The assent of the children is not required if:

(i) the IRB determines that the capability of some or all of the children involved in research under a particular research protocol is so limited that they cannot reasonably be consulted; or

(ii) the IRB determines that the intervention or procedures involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research; or

(iii) the IRB determines that the circumstances permit consent to be waived in accordance with A. (c), (d), and (f) above.

(b) The consent and assent requirements described in A. and B. above may be waived if:

(1) The IRB has determined that the research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), and,

(2) The waiver is not inconsistent with federal, state, and local laws and

(3) An appropriate mechanism for protecting the children who will participate as subjects in the research is substituted. (The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol; the risk and anticipated benefit to the research subjects; and their age, maturity, status, and condition.)

C. Consent Requirements for Research Involving Prisoners

(a) *In addition to* the consent requirements described in **A.** above, the following requirements apply to research involving prisoners:

Research on prisoners may be undertaken only if:

(1) Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research when making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and

(2) Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities, and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired.

D. Consent Requirements for Research Involving Pregnant Women and Fetuses

(a) *In addition to* the consent requirements described in **A.** above, the following requirements apply to research involving pregnant women and fetuses:

(1) Research directed toward pregnant women may be conducted only if the mother and father are legally competent and have given their informed consent after having been fully informed regarding possible impact on the fetus, except that the father's informed consent need not be secured if:

(i) the purpose of the research is to meet the health needs of the mother;

(ii) his identity or whereabouts cannot reasonably be ascertained;

(iii) he is not reasonably available; or

(iv) the pregnancy resulted from rape.

(2) Research directed toward fetuses *in utero* may be conducted only if the mother and father are legally competent and have given their informed consent, except that the father's informed consent need not be secured if:

(i) his identity or whereabouts cannot reasonably be ascertained;

(ii) he is not reasonably available; or

(iii) the pregnancy resulted from rape.

TABLE 2: HHS REQUIREMENTS* FOR INFORMED CONSENT

E. Documentation of Informed Consent

§ 46.117 Documentation of informed consent.

(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

(b) Except as provided in paragraph (c) of this section, the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by § 46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

(2) A "short form" written consent document stating that the elements of informed consent required by § 46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the "short form."

(c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

(d) When children are included as subjects in the research, permission by parents or guardians shall be documented in accordance with and to the extent required by (a) through (c) above. When the IRB determines that assent of the children is required, it shall also determine whether and how assent must be documented.

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* FDA requirements differ slightly: omitting E. (c) and specifying the documentation required when informed consent is waived in emergency situations.

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2. Confidentiality of Data

In all research involving human subjects, confidentiality of identifiable information is presumed and must be maintained unless the investigator obtains the express permission of the subject to do otherwise.

The University recognizes the rights of the subjects to be protected against injury or illegal invasions of their privacy and their interests as members of a free society in preserving their dignity. The more sensitive the material, the greater the care that must be exercised in obtaining, handling, and storing data. Ordinarily, the following requirements must be met, subject only to their applicability to the particular activity:

a. Questionnaires, inventories, interview schedules, and other data-gathering instruments and procedures should be carefully designed to limit the personal information to be acquired to that which is absolutely essential to the activity.

b. Data that include information which would reveal a subject's identity should be stored in files accessible only to the project investigator and his or her authorized staff or representatives.

c. As early as feasible, the data should be handled in coded form, i.e., the subject's name and information that would reveal his or her identity should be removed. Plans for the ultimate disposition of the data should be made; or if they are to be retained indefinitely, plans must be made for their continued security.

d. The identity of subjects must not be released except with their express permission.

e. Use of stored data or information, which was originally obtained for different purposes and which involves identifiable subjects, requires examination of the risk involved, a determination of whether the new use is within the scope of the original consent or whether obtaining additional consent is necessary and feasible, and provision for the preservation of anonymity of the subjects.

Data that are part of the public domain are not covered by the foregoing restrictions. (For research requiring prior review [see Part III], the material submitted for review must specify the provisions for maintaining the confidentiality of data and/or preserving the anonymity of subjects.)

3. Classification of Risk and Required Safeguards

a. Types of Risk

There are different risks inherent in different research procedures. Risk is most obvious in medical and behavioral science research

projects involving procedures which may induce a potentially harmful altered physical state or condition: surgical and biopsy procedures; the removal of organs or tissues; the administration of drugs or radiation; the use of indwelling catheters or electrodes; the requirement of strenuous physical exertion; subjection to deceit, public embarrassment, humiliation, or emotional stress.

There is a wide range of medical, social, and behavioral projects and activities which pose no immediate physical risk to the subject, e.g., those involving the use of personality inventories, interviews, questionnaires, observation, photographs, taped records, and stored data. However, some of these procedures may involve varying degrees of discomfort, harassment, or invasion of privacy, or they may constitute a threat to the subject's dignity through the imposition of demeaning conditions.

There are also medical and biomedical projects concerned solely with organs, tissues, body fluids, and other materials obtained in the course of routine performance of medical services, such as diagnosis, treatment, and care. The *use* of these materials obviously involves no element of physical risk to the subject. However, their use for many research, training, and service purposes may present psychological, social, or legal risks to the subject. In these cases, the key questions are whether the circumstances under which the materials were procured were appropriate and whether adequate and appropriate consent was, or can be, obtained for the use of these materials for project purposes.

Some studies depend upon stored data or information which was obtained for different purposes.

- If the materials to be used in the research involves *identifiable subjects,* the assessment of the risk involved must include a determination of whether the use of these materials is within the scope of the original consent, whether consent is necessary, and whether it can be obtained.
- If the material to be used in the research does *not* involve identifiable subjects, there is no risk to the subjects.

b. Classification of Risks

The human subjects involved in research conducted at or sponsored by the University of Illinois at Urbana-Champaign participate in a great variety of research projects. They range from classroom demonstrations where there are no risks beyond those associated with customary everyday existence to experimental studies of drugs, vaccines, radioactive materials, and severe physiological stresses where there is a definite risk. For the purposes of safeguarding the

human subjects and assuring that these safeguards are continuously provided, two classifications of risk are introduced:

i. Minimal Risk: The risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

ii. More Than Minimal Risk: The anticipated risks in the proposed research exceed, either in probability or magnitude, those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

All research protocols that involve procedures that may induce potentially harmful, altered psychological or physical states or conditions, untried diagnostic and surgical procedures or devices; biopsy procedures; removal of organs or tissues for study, reference, transplantation or banking; administration of drugs or radiation; use of indwelling catheters or indwelling electrodes; and procedures which require strenuous physical exertion fall in this category.

Several examples of uses of human subjects are cited in Tables 3 and 4, page 25, where the activities are classified according to these two categories of risk. These examples, which are merely illustrative, should serve as guides for the classification of future studies involving human subjects. In classifying research involving human subjects, the investigator and those who review the proposed use of subjects should not simply attempt to identify the research with these particular examples, but should follow the principles and procedures of this document in arriving at a carefully reasoned decision.

c. Specific Safeguards According to Risk Classification

The two categories of risk above require different safeguards for the rights and welfare of the subjects. Investigators, deans, directors, and department heads are responsible for assuring that these safeguards are provided accordingly.

i. For Activities Involving No More Than Minimal Risk

- Participation must be voluntary; but signed, written consent forms are not necessarily required.
- All subjects should be able to state that they have no disorder or defect contraindicating their participation in the proposed project. (Whether or not subjects are in fact asked to make such a statement will depend upon the nature of the project.)

- The project must be supervised by a qualified faculty or staff member who thereby assumes responsibility for the protection of the human subjects.

ii. For Activities Involving Greater Than Minimal Risk

- Participation must be voluntary and signed written consent forms are considered mandatory, unless another method for obtaining and documenting consent is specifically approved by the Institutional Review Board.
- A written record of the research detailing the procedures employed and the results obtained shall be made and kept for reference.
- The project must be supervised by a qualified faculty or staff member who thereby assumes responsibility for the protection of the human subjects.
- When the risk involved is a significant physical risk, the investigator and those who review his or her plans must determine:
  - — whether it will be necessary for the subjects' physical condition to be evaluated by a licensed physician who is acquainted with the possible hazards of the proposed investigations; and
  - — whether supervision or ready availability of a physician is advisable for the project.
- No form of radioactive material may be experimentally administered to human subjects without the authorization of the persons responsible to the University for the appropriate and safe use of radioactive material.
- No investigational new drugs (drugs not certified by FDA for clinical use) nor significant risk devices (as defined in 21 CFR 812.3 [m]) may be administered or used without compliance with the FDA requirements. The FDA requirements include appropriate notification to the FDA, receipt of either a waiver or permission from the FDA, and in the case of drugs, an *Investigations New Drug (IND)* number; in the case of a significant risk device, an *Investigational Device Exemption (IDE)* number.

TABLE 3: EXAMPLES OF RESEARCH INVOLVING MINIMAL RISK

1. Studies of the psychological and physiological effects of mild to moderate sleep loss.
2. Studies of movement and moderate exercise of asymptomatic children and adults where adverse effects are not anticipated.
3. Classroom experiments on physiological responses to moderate exercise, mild thermal stress, or breathing atmopheres with slightly reduced oxygen or slightly elevated carbon dioxide, etc.
4. Most psychological studies of learning, conditioning, sensory perception, personality, and group situations.
5. Psychological and judgment responses to speech.
6. Psychosocial studies of childhood obesity.
7. Behavioral studies of child development.
8. Corrective therapeutic exercise.
9. Industrial work studies with mild to moderate work load and mild to moderate thermal stress.
10. Clothing and textile studies under conditions of mild to moderate thermal stress.
11. Psychological studies of hypnosis where the subjects are not subjected to physiological or emotional stress. In this context, the volunteer under hypnosis will not be asked personal questions which relate to his private life.
12. Nutritional studies in which the subjects are expected to ingest neither unusual diets nor diets which are deficient in essential nutrients.
13. Taste panel studies and taste tests involving common food ingredients or known, edible materials.

TABLE 4: EXAMPLES OF RESEARCH INVOLVING MORE THAN MINIMAL RISK

1. Simulated high altitude flights.
2. Psychological studies of hypnosis where subjects are subjected to physiological or emotional stress.
3. Adult exercise and fitness testing where the imposed work load substantially exceeds the customary physical activity of the individual.
4. Industrial work studies where there is hard physical work and high environmental temperature.
5. Physiological studies of sweating involving special nutrient regimens, dehydration, and work in thermally stressful surroundings.
6. Pharmacological studies of prescribed drugs.
7. Studies involving introduction of cold viruses or the administration of vaccines and antibiotics.
8. Studies of the effects of prescribed tranquilizer drugs on driving skills.

Part III: Review Requirements: Applicability, Exemptions, and Procedures

1. Research conducted at or sponsored by the University of Illinois at Urbana-Champaign, whether subject to or exempt from prior review, must:

a. adhere to the Belmont Principles,

b. be in compliance with the Nuremberg Code or one of the ethical codes developed by the various professional associations, and

c. adhere to the policies and procedures set forth in this document.

All projects involving human subjects must observe the UIUC standards of informed consent and confidentiality of data.

2. Investigators are encouraged to consult with their peers regarding research protocols involving human subjects.

3. All research involving human subjects must be submitted for *prior review* in accordance with the IRB policies and procedures (see Section B which follows on page 35) *unless the only involvement* of human subjects will comply fully with the criteria for one or more of the exemption categories set forth in Section A which follows on page 28.

4. *Only UIUC faculty* (instructors, assistant professors, associate professors, and professors) *are eligible to make the determination of compliance with the exemption criteria.* Visiting faculty, students, teaching assistants, research assistants, research associates, and other staff must have their judgments regarding eligibility for exemption reviewed by the faculty member who shall accept responsibility for that decision.

5. The moral and legal burden of the protection of human subjects in work involving research in the exempted categories lies with the responsible principal investigator, i.e., the qualified faculty or staff member supervising the work.

6. Investigators may *request* review of exempted work and are encouraged to do so if they are uncertain about whether or not the project qualifies for exemption or if they wish the advice of the Institutional Review Board (333-2670).

7. The Institutional Review Board reserves the right to require review of specific research activities or classes of research activities even

though they qualify for exemption. Exercise of such oversight will rarely be necessary. Requirements of sponsoring agencies, unexpected problems, and the need to evaluate experiences with exemption categories might trigger such review.

Note: For HHS funded work, the submission of Form HHS-596 (Protection of Human Subjects Assurance/Certification/Declaration), signed by the Executive Secretary of the IRB, is still required for all research involving human subjects, *whether it is exempt or not.* For work that is exempt:

- check the last box in item 5 of the Certification Form, and
- enter the HHS identification number for the exemption claimed on the line provided.

HHS identification numbers are given in the following list of exemption categories (Section A).

HHS has warned that an inappropriate claim for exemption may lead to delays in processing an application for funding.

A. Exemption Criteria*

Research may be exempted from prior review if the only involvement of human subjects will be in one or more of the following categories and will not be excluded by the limitations for the specific category(s):

Exemption Category	*Limitations*
1. HHS Identification 46.101(b)1 Research conducted in *established or commonly accepted educational settings,* involving *normal educational practices* such as *a.* research on regular and special education instructional strategies, or *b.* research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.	Such work can be exempted only if the investigator believes that the research protocol will place the subjects at no more than minimal risk. The consent of authorized school official(s) can serve in lieu of consent of the individual subjects, but consent must be obtained in an appropriate way. If subjects are children with the capacity to give assent, normally their assent must also be solicited. (See Part II, Section D1, pages 12-16.) Confidentiality of identifiable information must be maintained without the express permission of the subjects to do otherwise. (See Part II, Section D2, page 21.) If the work is governed by HHS regulations, this exemption does *not* apply to research involving prisoners or research *directed* toward pregnant women as subjects.
2. HHS Identification 46.101(b)2 Research involving the use of *educational tests* (cognitive, diagnostic, aptitude, achievement) if information taken from these sources is recorded in such a manner that subjects cannot be identified, either directly or through the identifiers linked to the subjects. Subjects will be considered *unidentifiable* if the investigator has no way to link the data with individual subjects.	Such work can be exempted only if the investigator believes that the research protocol will place the subjects at no more than minimal risk. If the research is undertaken in a commonly accepted educational setting, the consent of authorized school official(s) can serve in lieu of consent of the individual subjects. Otherwise, consent of the subjects or their authorized representatives must be obtained. If subjects are children with the capacity to give assent, normally their assent must also be solicited. (See Part II, Section D1, pages 12-16.) If the work is governed by HHS regulations, this exemption does *not* apply to research involving prisoners or research *directed* toward pregnant women.

* *Note:* Only faculty members and IRB staff are eligible to make the determinations of compliance with the exemption criteria.

For assistance in interpreting the categories and the limitations on their use, call the IRB office at 333-2670.

Exemption Category (Continued)

3. HHS Identification 46.101(b)3

Research involving *survey* or *interview* procedures,* except where *all* of the following conditions exist:

a. responses are recorded in such a manner that human subjects can be *identified,* directly or through identifiers linked to the subjects, and

b. the subject's responses, if they became known outside the research, could reasonably place the subject *at risk of criminal or civil liability or be damaging to the subject's financial standing or employability,* and

c. the research deals with *sensitive aspects of the subject's own behavior,* such as illegal conduct, drug use, sexual behavior, or use of alcohol.

NOTE: Such projects require prior review only if *all three conditions* exist.

All research involving survey or interview procedures is exempt, without exception, when the respondents are elected or appointed *public officials or candidates for public office.*

Limitations (Continued)

Such work can be exempted only if the investigator believes that the research protocol will place the subjects at no more than minimal risk.

Consent of the subject, or the subject's representative, is required. If subjects are children with the capacity to give assent, normally their assent must also be solicited.

If the work is governed by HHS regulations, this exemption does *not* apply to research involving prisoners or children, or research *directed* toward pregnant women as subjects.

Confidentiality of identifiable information must be maintained without the express permission of the subjects to do otherwise.

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* The words *survey* and *interview* are defined as follows.

Survey: (n.) A sampling, or partial collection of facts, figures, or opinions taken and used to approximate or indicate what a complete collection and analysis might reveal.

Interview: (n.) A formal meeting in which a person or persons question, consult, or evaluate another, or others; (v.t.) To have an interview with in order to question, consult, evaluate, or seek information from.

The use of survey or interview procedures occurs in a wide variety of research activities even though the terms *survey* or *interview* may not actually be used by the investigators in describing their work. For example, (1) descriptive studies in which the methodology is elicitation of linguistic data by the classical techniques of linguistics, or (2) descriptive (*as opposed to experimental*) studies of cognitive understanding, personality, social perception, affect, and attitude.

Exemption Category (Continued)	*Limitations (Continued)*
4. HHS Identification 46.101(b)4 Research involving *observation* (including observation by participants) *of public behavior,* except where *all* of the following conditions exist: *a.* observations are recorded in such a manner that human subjects can be *identified,* directly or through identifiers linked to the subjects, and *b.* the observations recorded about the individual, if they became known outside the research, could reasonably place the subject *at risk of criminal or civil liability or be damaging to the subject's financial standing or employability,* and *c. the research deals with sensitive aspects of the subject's own behavior,* such as illegal conduct, drug use, sexual behavior, or use of alcohol. *NOTE:* Such projects require prior review only if *all three conditions* exist.	Such work can be exempted only if the investigator believes that the research protocol will place the subjects at no more than minimal risk. The consent of the subjects is implied by their presence in a public place. (See Part II, Section D1, pages 12-16.) If the work is governed by HHS regulations, this exemption does not apply to: *a.* research involving prisoners, *b.* research involving children where the investigator(s) participates in the activities being observed, or *c.* research *directed* toward pregnant women as subjects. The confidentiality of identifiable information must be maintained without the express permission of the subjects to do otherwise. (See Part II, Section D2, page 21.)
5. HHS Identification 46.101(b)5 Research involving the collection or study of *existing* data, documents, records, pathological specimens, or diagnostic specimens, if these sources are *publicly available* or if the information is recorded by the investigator in such a manner that *subjects cannot be identified,* directly or through identifiers linked to the subjects.	Such work can be exempted only if the investigator believes that the research protocol will place the subjects at no more than minimal risk. The requirement for consent of the subjects is waived if the data, documents, records, or specimens, etc., are publicly available. The authorization of the custodian of the data, etc., can serve in lieu of specific subject consent for access to data, etc., which are *not* publicly available. In such cases, the investigator must be satisfied that the custodian is authorized to release the data, etc., for research purposes. If work is governed by HHS regulations, this exemption does not apply to research involving prisoners or for research *directed* toward pregnant women.

Exemption Category (Continued)

6. HHS Identification 46.101(b)6

Research and demonstration projects which are conducted by or subject to the approval of the Department of Health and Human Services, and which are designed to study, evaluate, or otherwise examine

a. programs under the Social Security Act, or other public benefit or service programs;

b. procedures for obtaining benefits or services under those programs;

c. possible changes in or alternatives to those programs or procedures;

d. possible changes in methods or levels of payment for benefits or services under those programs.

Limitations (Continued)

Such work cannot be exempted if prior review is specifically required by statute, or if the Secretary of HHS determines that a research or demonstration project presents a danger to the physical, mental, or emotional well-being of a participant or subject of the research or demonstration project.

If the work is governed by HHS regulations, this exemption does not apply to research involving prisoners or to research *directed* toward pregnant women.

The UIUC requirement for informed consent can be waived if:

a. the research could not be carried out practicably without the waiver, and

b. the Secretary of HHS has not determined that the project presents a danger to a participant or subject.

Exemption Categories A through I cannot be used for work funded by HHS or other agencies which require adherence to FDA or HHS regulations.

Exemption Category	*Limitations*
A. Collection of: hair and nail clippings, in a nondisfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction.	Such work can be exempted only if the investigator believes that the subjects involved are in good health and that the research will not place the subjects at more than minimal risk. Consent of the subject or the subject's representative must be obtained. If subjects are children with the capacity to give assent, normally their assent must be solicited. (See Part II, Section D1, pages 12-16.) Confidentiality of identifiable information must be maintained unless the express permission of the subject is given to do otherwise. (See Part II, Section D2, page 21.) This exemption cannot be used for work funded by HHS or other agencies governed by HHS or FDA regulations.
B. Collection of excreta and external secretions, including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during delivery.	Same as for Exemption Category A.
C. Recording of data from subjects *eighteen years of age or older* using *noninvasive* procedures *routinely* employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. It also includes procedures such as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does *not* include exposure to electromagnetic radiation outside the visible range (for example, X-rays or microwaves).	Same as for Exemption Category A. This exemption does not apply to research involving pregnant women.

Exemption Category (Continued)	*Limitations (Continued)*
D. Collection of blood samples by venipuncture, in amounts not exceeding a total of four hundred fifty milliliters in an eight-week period, and no more often than two times per week from subjects *eighteen years of age or older* who are in good health and *not pregnant.*	Same as for Exemption Category A.
E. Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.	Same as for Exemption Category A.
F. Voice recordings made for research purposes such as investigations of speech defects.	Same as for Exemption Category A.
G. Moderate exercise by healthy volunteers.	Same as for Exemption Category A. This exemption does not apply to research involving pregnant women.
H. Research on individual or group characteristics or behavior (such as studies of perception, personality, social interaction, affect or attitude) which does *not* involve either of the following: *a.* stress to the subjects, including use or threat of noxious or aversive stimuli, *or* *b.* intentional, clearly nontransitory alteration of the subject's emotional state or behavior.	Such work can be exempted only if the investigator believes that the subjects involved are in good health and that the research will not place the subjects at more than minimal risk. Consent of the subjects or the subject's representative must be obtained. If subjects are children with the capacity to give assent, normally their assent must be solicited. Note that deception is permitted only under certain circumstances. (See Part II, Section D1, pages 12-16.) Confidentiality of identifiable information must be maintained unless the express permission of the subjects is given to do otherwise. (See Part II, Section D2, page 21.) This exemption cannot be used for work governed by HHS or FDA regulations.

Exemption Category (Continued)

I. The study of existing data, documents, records, pathological specimens, or diagnostic specimens if the original collection of the data would have been exempt under one or more of the other exemption categories described above.

Note: This exemption category is an expansion of exemption category 5. If the investigator does not know how the original data, etc., were obtained, or if the research does not fall within exemption category 5, it must be submitted for prior review.

Limitations (Continued)

Such work can be exempted only if the investigator believes that the research will not place the original subjects at more than minimal risk.

The consent of the subjects from whom the data, documents, records, or specimens were originally obtained is waived if the data, etc., are publicly available. The authorization of the custodian of the data, etc., will serve in lieu of specific subject consent for data, etc., which are *not* publicly available. In such cases, the investigator must be satisfied that the custodian is authorized to release the data, etc., for the research purpose. Otherwise, consent of the subjects must be obtained.

Confidentiality of identifiable information must be maintained unless the express permission of the subjects is given to do otherwise. (See Part II, Section D2, page 21.)

This exemption cannot be used for work governed by HHS or FDA regulations.

B. Prior Review Process for Nonexempt Research

Much of the research undertaken at the University of Illinois at Urbana-Champaign involves no more than minimal risk. A considerable amount of the research involving human subjects here is undertaken without external support. The University has developed a partially decentralized process for review of research involving subjects where that research is not externally funded and places the subjects at no more than minimal risk.

Departments which have a large volume of research involving human subjects which is neither externally funded nor involves research above minimal risk have been invited to develop and submit for IRB approval departmental guidelines for decentralized review of such work. Given the satisfactory experience with this system for a period of six years, the partially decentralized review procedures will be continued. Those departments with approved guidelines must follow the revised IRB policies and procedures given in this document. A list of departments which have IRB approved guidelines is available from the office of the Institutional Review Board (333-2670).

Research in departments which do *not* have IRB approved guidelines, which involves external support, or which places subjects at more than minimal risk must be submitted to the central Institutional Review Board for prior review.

Table 5 summarizes the criteria which determine the locus of review. Figure 1 summarizes the review process.

Results of reviews conducted by central IRB will be provided to the Project Director in writing by the Executive Secretary of the IRB. Results of reviews conducted by IRB-approved departmental review processes will be communicated in accordance with departmental practice. For further information, check with the Departmental Executive Officer.

If either the IRB review or IRB-approved departmental review process results in the disapproval of or a major change in a research activity, the review body will provide a written statement of the reasons for its decision and will give the investigator an opportunity to respond either in person or in writing. Actions of the IRB-approved departmental review process may be appealed to the central IRB.

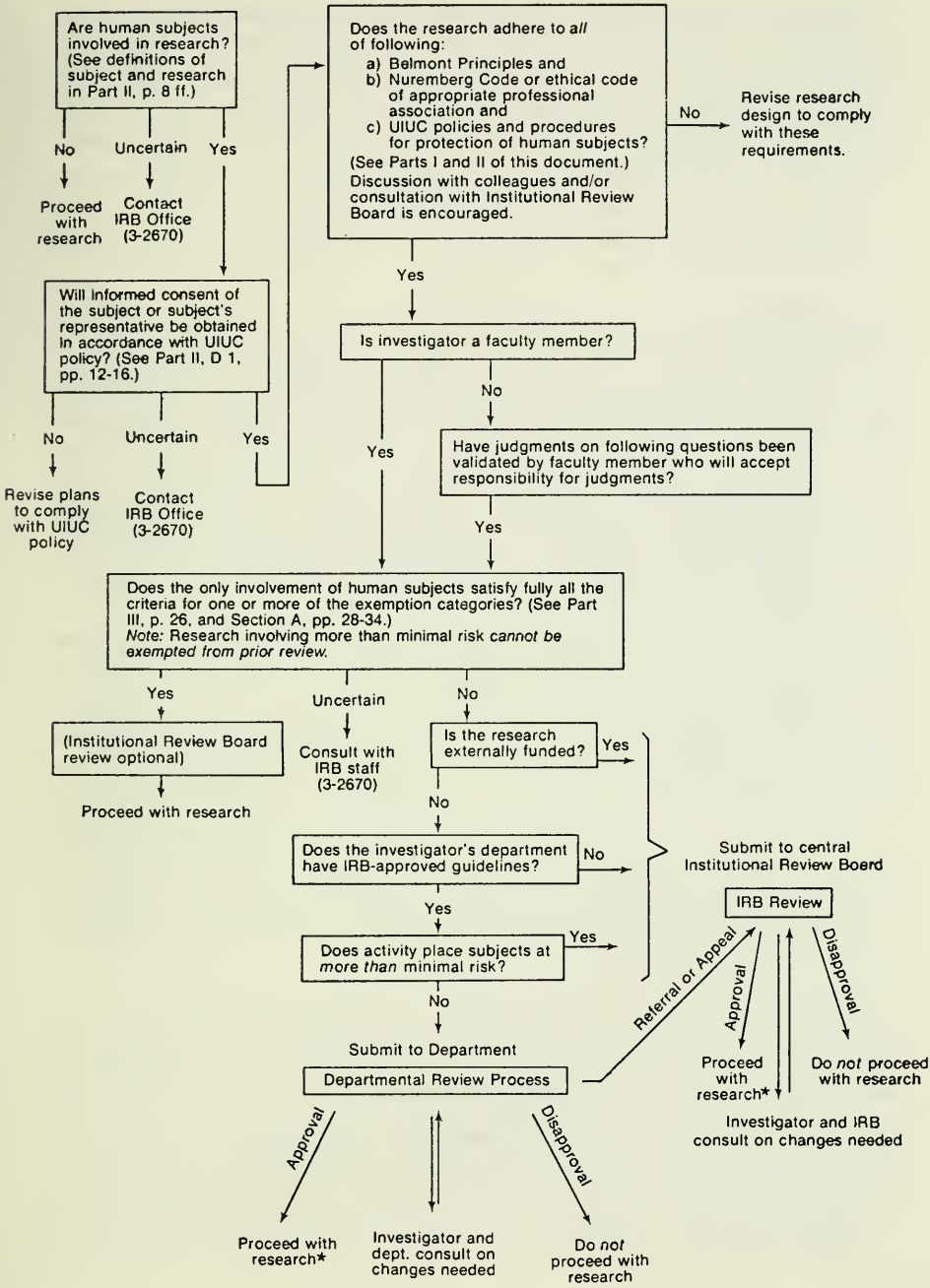
Note: Approvals by the central IRB or IRB-approved departmental review process are valid for *one year* unless a shorter period is specified. All research subject to prior initial review is subject to continuing review requirements described in Section III, G, pages 45 and 46.

(Text continues on page 38.)

TABLE 5: UIUC REVIEW REQUIREMENTS

Type of Research	*Locus of Review*
1. Exempt research, that is research in which the *only involvement* of human subjects will comply fully with criteria for one or more of the exempted categories. (See Part III, page 26 and Section A, pages 28-34.)	Responsible *faculty* investigator (Consultation with colleagues encouraged; IRB review available on request.)
2. All nonexempt research which is *externally* funded, regardless of the level of risk involved.	central Institutional Review Board
3. All nonexempt research which places subjects at *more than* minimal risk, regardless of the source of funds.	central Institutional Review Board
4. All nonexempt research in departments which do *not* have IRB-approved guidelines for decentralized review, regardless of the level of risks involved or the source of funds.	central Institutional Review Board
5. Research which meets *all* of the following requirements: *a.* Is undertaken in a department which has IRB-approved guidelines for decentralized review, and *b.* is *not* externally funded, and *c.* does *not* place subjects at more than minimal risk, and *d.* is not exempt.	IRB-approved departmental review procedures

FIGURE 1: THE REVIEW PROCESS FOR RESEARCH ACTIVITIES



*Note: Approvals by the central IRB or IRB-approved departmental review process are valid for one year, unless a shorter period is specified.
All research subject to prior initial review is subject to continuing review requirements described in Section III, G.

C. Timing of Review

Review must occur *prior* to the initiation of activity and *prior* to implementation of changes in procedures involving human subjects (unless the research is necessary to eliminate apparent immediate hazards to the human subjects) and *at least annually* during the lifetime of the project. If the project is being proposed for external funding, review should take place prior to or shortly after submission of the proposal to the funding agency. Some funding agencies have imposed deadlines for submission of the certification of IRB review and approval. For example, HHS has set a deadline of 60 days after proposal submission.[1]

1. Indefinite Plans

Certain types of research, particularly externally funded research, are initiated with the knowledge that human subjects may be involved but without definite plans at the time of research initiation or research proposal submission. For example, institutional type grants where selection of specific projects is the institution's responsibility; research training grants where trainee activities involving subjects remain to be selected; and projects in which the human subjects' involvement will depend on completion of instruments, prior animal studies, or purification of compounds, etc.

Proposals for research with indefinite plans involving use of human subjects do not need prior review. Although such research may be initiated and an award of external support may be made prior to the development of definite plans for involving human subjects, *no human subjects may be involved in any research* until the project has been reviewed and approved in accordance with IRB policies and procedures. Funding agencies governed by the HHS regulations require that work with human subjects not be initiated until certification of review has been submitted to the sponsor, unless the work is exempt from prior review. (See Exemption Categories, Part III, Section A, pages 28-31.)

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[1] For National Institutes of Health (NIH) applications, an HHS-596 Form must be submitted *with the application,* unless institutional review is unavoidably delayed beyond submission of the application. In such a case, enter "Pending" on the HHS-596 Form and provide an explanation. A follow-up HHS form must then be submitted *and received* within 60 days after the receipt date for which the application is submitted. Any modifications of the Research Plan section of the application are to be submitted with the follow-up HHS-596 Form. *Note:* If certification is not received within the 60 day period, the application will be considered incomplete and will be deferred for a later review. To assure receipt in time, provide the IRB office with the name of the initial review group (IRG) to which the application has been assigned by NIH.

2. Change from "No Human Subjects" to the "Use of Human Subjects"
Occasionally an investigator undertakes research *without* the intention of involving subjects, but he or she later decides to use human subjects in the research. Before work with human subjects can begin, the research must be reviewed in accordance with IRB approved policies and procedures. For work funded by agencies governed by the HHS regulations, approval of the proposed change to use human subjects must be given by the agency as well.

D. Expedited Review

Some categories of research that require review by the central Institutional Review Board may be reviewed through an expedited review procedure. The Institutional Review Board will determine what specific types of research are eligible for the expedited procedure and will restrict its use to research involving no more than minimal risk. Work funded by agencies governed by the HHS regulations will be eligible for the expedited review provided that it meets the UIUC's IRB requirements and also meets the HHS criteria for expedited review. The IRB may also use the expedited review procedure to review minor changes in previously approved research during the period for which the original approval is authorized.

Research which meets the specific criteria for exemption in Part III, Section A, but does not satisfy all of the limitations given for the specific exemption category, may be eligible for expedited review unless the research is governed by regulations which do not permit it. For example, FDA regulations do not allow an expedited review for testing sensory acuity in Exemption Category C or for any research in Exemption Category H. (See pages 32 and 33.)

From the investigator's perspective, an expedited review will differ from a regular review only in the length of time required for the review. The same review materials must be submitted for an expedited review as for a regular review and they should be directed to the same review body.

Under the expedited review procedure, the IRB review will be carried out by specific IRB members assigned according to their expertise by the Chairperson. The assigned reviewer will report the decision to the Executive Secretary. If the recommendation is for approval, the decision will be communicated immediately to the investigator and will be reported at the next IRB meeting. If the decision is for disapproval or a major change, the proposed research will be placed on the agenda for full IRB discussion.

E. Criteria for IRB Approval of Nonexempt Research

These criteria apply whether the research is reviewed by the central Institutional Review Board or under IRB-approved departmental guidelines. For work supported by agencies governed by the HHS regulations, certain specific criteria are required in addition to those required by the UIUC policy. Tables 6A and 6B give the UIUC criteria and the HHS criteria.

The IRB staff will help identify other agency requirements.

F. Materials to Be Submitted for Prior Review

The materials submitted to the central Institutional Review Board or the IRB-approved departmental review body must provide sufficient information for the reviewers to assure that the criteria for approval in Tables 6A and 6B are met.

1. Form IRB-1

Form IRB-1, Information for Review of Research Involving Human Subjects, must be submitted for all activities to be reviewed by the central Institutional Review Board. Its use in departmental review of nonexternally funded activities falling within IRB-approved departmental guidelines is optional, but the information required for that review must be presented in full. Form IRB-1 calls for administrative information, certain classifying data, and responses to several specific requests for information about the proposed research, the proposed use of subjects, and provisions to assure protection of the rights and welfare of the subjects.

The investigator's responses should be prepared with IRB readers in mind. Answers should be brief and concise, but complete. The materials submitted for review must demonstrate the investigator's comprehension of the UIUC policies, standards, and procedures, and his or her recognition of responsibility for the protection of human subjects in research. Inadequate information causes delays in the review process.

2. Additional Information

Certain types of projects require submission of special information such as the following:

a. If subjects will include children, prisoners, pregnant women, or fetuses, special care must be taken to describe plans for soliciting consent/assent. For research involving children who are capable of assent, the investigator should describe what the child will be

(Text continues on page 44.)

TABLE 6A: UIUC CRITERIA FOR IRB APPROVAL*

UIUC

The IRB shall review whether:

1. The proposed research is consistent with the Belmont Principles and the Nuremberg Code, or one of the ethical codes of the professional associations, and adheres to the UIUC policy stated in Part II of this document. (See page 5 ff.)
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to the subjects and the importance of the knowledge that may be reasonably expected to result.

   In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should *not* consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of research on public policy) as among those research risks that fall within the purview of its responsibility.
3. Selection of the subjects is equitable. In making this assessment, the IRB should take into account the purposes of the research and the setting in which the research will be conducted.
4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative. If subjects are children and if they are capable of giving assent, adequate provisions will be made to solicit their assent as well as the permission of their parents or authorized representative. Consent will be obtained in accordance with and to the extent required by Section D1 of this document. (See page 12 ff.)
5. Informed consent will be appropriately documented, in accordance with, and to the extent required by Part I, Section D1, page 15 ff.
6. Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
7. Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. Unless subjects are expressly informed otherwise, confidentiality of records will be required.
8. Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, appropriate additional safeguards have been included in the study to protect the rights and welfare of these subjects.

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* See Table 6B for criteria applicable to research governed by HHS regulations.

TABLE 6B: CRITERIA FOR IRB APPROVAL OF RESEARCH GOVERNED BY HHS REGULATIONS

HHS

In order to approve research covered by these regulations, the IRB shall determine that all of the following requirements are satisfied:

1. Risks to subjects are minimized:
   a. by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
   b. whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.

   In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should *not* consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
3. Selection of subjects is equitable. In making this assessment, the IRB should take into account the purposes of the research and the setting in which the research will be conducted.
4. Informed consent will be sought from each prospective subject, or the subject's legally authorized representative, in accordance with and to the extent required by Section 46.116, HHS regulations. (See Table 1, pages 16-19 of this document.) If subjects are children and if they are capable of giving assent, adequate provisions will be made to solicit their assent as well as the permission of their parents or authorized representative. (See items 9 through 13 below.)
5. Informed consent will be appropriately documented, in accordance with and to the extent required by Section 46.117 of HHS regulations. See Table 2, page 20 of this document.)
6. Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
7. Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
8. Where some or all of the subjects are likely to be vulnerable or coercion or undue influence, such as persons with acute or severe physical or mental illness or persons who are economically or educationally disadvantaged, appropriate additional safeguards have been included in the study to protect the rights and welfare of these subjects.
9. When children are included in any research:
   a. Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians as set forth in Table 1. (See page 18.)

The IRB will judge whether children are capable of providing assent, taking into account the ages, maturity, and psychological state of the children involved and will determine how assent must be documented.

b. Where parental permission is required, the IRB will determine when permission of one parent is sufficient, in accordance with HHS requirements described in Appendix IV, Section A, 1-*b*.

The IRB will determine when the assent and consent requirement may be waived, in accordance with HHS consent requirements listed in Table 1, pages 17-19.

10. When children are included in research in which more than minimal risk is presented by an intervention or procedure that holds out the prospect of direct benefit to the individual subject or by a monitoring procedure that is likely to contribute to the subject's well-being,

a. the risk is justified by the anticipated benefit to the subjects, and

b. the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches.

11. When children are included in research in which more than minimal risk to children is presented by an intervention or procedure that does *not* hold out the prospect of direct benefit to the individual subject or by a monitoring procedure that is *not* likely to contribute to the well-being of the subject,

a. the risk represents a minor increase over minimal risk;

b. the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations; and

c. the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition that is of vital importance for the understanding or amelioration of the subjects' disorder or condition.

12. When children are included in plans for research not otherwise approvable,

a. the IRB must find that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children, and

b. the Secretary of HHS after consultation with a panel of experts in pertinent disciplines (e.g., science, medicine, education, ethics, law) and following an opportunity for public review and comment, must determine either that the research in fact is approvable by the IRB or

i. the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem that affects the health or welfare of children; and

ii. the research will be conducted in accordance with sound ethical principles; and

iii. adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians.

13. When children who are wards of the state or any other agency, institution, or entity are included in research

a. involving more than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subjects' disorder or condition, or

b. not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children, the IRB must determine that the research is

   i. related to their status as wards or

   ii. conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards

and the IRB will require the appointment of an advocate for each child who is a ward. All other determinations required for research must also be made. (See above.)

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told about the research, how the information will be presented to him or her, and how assent will be solicited. The information presented to the child will vary from a simple description of what the child will experience to the equivalent of the information that would be presented to an adult subject. Younger and less sophisticated children will be given simple information on what they will experience as they participate in the research. For older and more sophisticated children, more detailed information will be given, together with a statement that the project is for the purpose of research. All children must be informed that they may withdraw from participation at any time.

b. If a written consent form or written explanation of the project is used, submit a copy of a sample form or explanation.

c. If any initial deception is involved to avoid invalidation or biasing of the research, indicate what information will be withheld and why incomplete disclosure is justified. Also describe the debriefing procedure to be used, if any.

d. If subjects are to receive payment or other incentives for participation, describe such incentives.

e. If access to subjects is gained through cooperating institutions not under the control of the University, identify the institutions and describe the method for assuring that the authorized official of that institution is informed of the study. (If such subjects are placed at more than minimal risk, *documentation* of the institutional approval will be required. See *k* below.)

Projects which place subjects at *more than minimal risk* require the following additional information:

f. State the justification for use of human subjects.

g. Provide the basis for the investigator's assessment of benefits, risks, and adequacy of precautions taken to minimize risks. (Citation of relevant prior work is helpful.)

h. Attach copies of sample consent forms to be used and any written or oral explanation to be given to the subjects. If the project presents risks of physical injury, the consent form must include a statement as to whether any compensation or medical treatment is available if injury occurs, and, if so, what they consist of and where further information may be obtained.

i. If drugs are to be administered, identify the drug, indicate whether or not it is FDA-certified *for this purpose;* state the dosage to be administered, who will administer the drug, the period of administration, and the anticipated effects. If the drug is not FDA-certified for this purpose, submit a copy of FDA Form 1571, Investigational New Drug Certification.

j. If a significant risk device is to be used, identify the device and whether or not it is FDA approved for this purpose; state the provisions for the use of the device, who will administer it, the period of administration, and the anticipated effects. If the device has not been approved by the FDA for this purpose, submit a copy of an Investigational Device Exemption (IDE) Application which has been sent to the Food and Drug Administration.

k. Document institutional authorization for access to subjects if access to subjects is gained from a cooperating institution (provide status of subjects; number of subjects; age range of subjects; name and address of cooperating institution; name of authorizing official of cooperating institution; title, official signature, and telephone number of authorizing official).

In summary, the materials submitted for review must be presented in sufficient detail for the IRB or IRB-approved departmental reviewers to make a fair and responsible independent judgment as to the protection provided for the subjects and the project's compliance with UIUC policies, standards, and procedures as well as applicable laws and regulations of external agencies.

G. Continuing Review

The IRB and the IRB-approved departmental review bodies will conduct a continuing review of nonexempt research at intervals appropriate to the degree of risk, but no less frequently than once per year. The review interval will be specified in the notification to the investigator regarding the results of the initial review. The minimum requirements for a contin-

uing review will include an inquiry regarding the investigator's plans for continuing the research beyond the original period, modifications to the original protocol, occurrence of any problems involving human subjects, and consideration of the applicability of any changes in external or UIUC review requirements. The IRB may also impose special requirements in specific cases, such as a requirement for a progress report, third party review of the consent process, or third party review of the research. Such specific requirements will normally be stipulated in the original approval letter.

Although the investigator is responsible for initiating the annual continuing review, the IRB or departmental review process should normally provide a reminder of the necessity for continuing review and any forms to be used for this purpose.

H. Review of Cooperative Research

Cooperative projects may involve distribution of responsibility for aspects of the research or distribution of access to subjects among cooperating investigators and/or institutions. UIUC policies and procedures must be followed for all aspects of cooperative research which are conducted at or sponsored by the University of Illinois at Urbana-Champaign. Where the work is externally sponsored, the external sponsor's requirements must be followed by every investigator and institution receiving such external support. When the UIUC is the prime grantee or contractor, the UIUC is responsible to the sponsor for safeguarding the rights and welfare of the human subjects.

The UIUC may use joint review, reliance upon the review of another qualified IRB, or similar arrangements to avoid duplication of effort. Such special arrangements must be made well in advance through consultation with the Executive Secretary of the IRB.

I. Records of Review

The review of nonexempt research must be documented. These records must be retained for three years after the completion of the research. They must be accessible for inspection and copying by authorized representatives of the University or the sponsoring agencies.

1. Records to be retained by IRB or IRB-approved departmental review group:
   a. Materials submitted for review
   b. Identity of reviewer(s)
   c. Actions taken and basis for requiring changes or disapproval
   d. Record of continuing review activities

e. Correspondence between investigator and review body

f. Written guidelines for operation of the review body

g. Statements of significant new findings provided to subjects, where required

2. Records to be retained by investigator:

a. Copies of signed consent documents (see also pages 15 and 16)

b. Written record of the research detailing the procedures employed and the results obtained

J. Suspension or Termination of IRB Approval of Research

The central IRB has the authority to suspend or terminate approval of any research conducted at or sponsored by the University of Illinois at Urbana-Champaign that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval will include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator and the appropriate institutional officials. For any HHS supported work so terminated, HHS regulations require that the Secretary of HHS be notified as well.

K. Institutional Oversight

Research that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. Institutional officials may *not* approve the research if it has been *disapproved* by the IRB.

Research that has been approved by an IRB-approved departmental review process may be subject to further appropriate review and approval or disapproval by the central IRB and/or officials of the institution.

Part IV: Distribution of Responsibility

The responsibility for the protection of subjects in research is distributed among several parties: principal and coprincipal investigators, department heads and departmental review bodies, the Institutional Review Board, the University administration, sponsoring agencies, the subjects themselves, and those who control access to subjects.

A. Principal Investigator

The primary responsibility for the day-to-day assurance for protection of the rights and welfare of human subjects lies with the individual responsible for the conduct of the activity, i.e., the principal investigator. Specifically, the investigator is responsible for:

- Careful research design
- Careful adherence to ethical codes and applicable policies and procedures of the UIUC, the sponsoring agency, and cooperating institutions, if any
- Training and supervision of staff and students participating in the research
- Providing information required and taking all steps in initial and continuing review of nonexempt research
- Retaining required records
- Obtaining *prior* approval of IRB (or IRB-approved departmental review body) for changes in a nonexempt research activity
- Prompt reporting to the IRB of unanticipated problems involving risks to subjects or others

B. Departmental Executive Officer

The Executive Officer of the department has the responsibility to:

- Assure that faculty, staff, and students are kept informed of the UIUC policy and procedures and of their responsibilities for protecting the rights and welfare of human subjects involved in research
- Assure that the departmental review process, if any, operates within IRB-approved guidelines
- Assure that for any course offered by the department in which participation of the registrants as human subjects is expected, notification to this effect is given in the course description in the official University bulletins and timetables
- Report promptly to the IRB any unanticipated problems involving risks to subjects or others

C. Institutional Review Board and IRB-Approved Departmental Review Bodies

The IRB and IRB-approved departmental review bodies are responsible for:

- Initial and continuing review of nonexempt research
- Ascertaining acceptability of proposed research in terms of institutional commitments, applicable law, and standards of professional conduct and practice
- Documentation of such review in conformity with applicable law, regulations, and policies
- Provision of advice and counsel to investigators engaged in research involving human subjects

In addition, the IRB has responsibilities for:

- Developing policy, procedures, information, and instructions
- Adjudication of differences and review of problems arising in research involving human subjects
- Assuring compliance with externally imposed policies and regulations
- Reporting to the Executive Secretary unanticipated problems involving risks to subjects and others in work funded by HHS
- Reporting to the appropriate institutional officials and, for research funded by the HHS regulations, to the Secretary of HHS, any serious or continuing noncompliance by investigators with the requirements and determinations of the IRB

D. Sponsoring Agencies

Sponsoring agencies usually accept responsibility for evaluating research proposed for their support. This evaluation is undertaken in addition to that provided locally. The agency may impose additional conditions prior to or at the time of funding if additional conditions are judged to be necessary for the protection of human subjects. Furthermore, the agency may require that its funding for any project be terminated or suspended if it finds that the institution has materially failed to comply with the terms of its regulations.

E. Subjects

Subjects who participate in research should:

- Consider carefully the decision to participate in research
- Ask questions freely

- Recognize that they are free to withdraw from participation at any time
- Notify the investigator promptly of adverse effects of participation
- Take unresolved complaints or concerns about their participation in research to the Executive Officer of the Department and, if the matter remains unresolved, to the Executive Secretary of the Institutional Review Board

F. Individual or Institution Providing Access to Subjects

If the individual responsible for conduct of the activity is not a UIUC employee or student but is obtaining access to subjects through UIUC, *the individual providing access* to the subjects is responsible for assuring that UIUC policies and procedures, including review requirements, are met.

If professional practitioners or service agencies provide access to subjects, the individual providing access should assure that the professional's commitments to the client are not abridged.

If access is obtained through cooperating institutions, the authorized official of the institution must be informed of the research and should satisfy himself or herself that the subjects' rights and welfare will be protected and that institutional commitments to the subjects will not be abridged.

Part V: Administration of the UIUC Policies and Procedures

The UIUC principles for responsible use of human subjects in research, formulated in 1964, were originally administered in a totally decentralized manner consistent with the relatively low level of such activities and the decentralized nature of the institution. Over the years, the increase in the level of such activities and the increasing specificity of sponsored agencies' regulations made a totally decentralized administration unworkable. In 1975, a central Institutional Review Board was established and responsibility for assurance of the protection of human subjects was placed on that body. The Institutional Review Board developed a mechanism for sharing the review task in order to accommodate the very large number of projects which posed no more than minimal risk to the subjects. The partially decentralized review strengthens the disciplinary expertise of the review and enhances the accountability for protection of subjects. The Institutional Review Board and the IRB-approved departmental review bodies are described below.

A. The UIUC Institutional Review Board

The Institutional Review Board serves as the primary locus of institutional authority and responsibility for activities involving the use of human subjects. Its responsibilities include:

- Development of policy and procedures for review of such activities
- Development of information and instructions for investigators, reviewers, and subjects involved with such activities
- Initial and continuing review of such activities
- Ascertaining acceptability of proposed research in terms of institutional commitments, applicable law, and standards of professional conduct and practice
- Documentation of review of such activities in conformity with applicable law, regulations, and policies
- Provision of advice and counsel to investigators engaged in such activities
- Adjudication of differences and review of problems arising out of such activities
- Assuring compliance with externally imposed policies and regulations
- Reporting to the Secretary of HHS unanticipated problems involving risks to subjects and others, in work funded by HHS

- Reporting to the appropriate institutional officials and, for research funded by the HHS regulations, to the Secretary of HHS, any serious or continuing noncompliance by investigators with the requirements and determination of the IRB

As such, it serves the needs of a complex institution and is able to assure that externally imposed regulations are followed.

1. Composition of the IRB and Selection of Its Members

The UIUC Institutional Review Board shall have at least five members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. Members will be chosen so that the Institutional Review Board will be sufficiently qualified to:

- promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects and
- ascertain the acceptability of proposed research in terms of institutional commitments in regulations, applicable law, and standards of professional conduct in practice.

The following factors will be considered in selecting members:

- experience and expertise and
- diversity of background, including consideration of the racial and cultural background and sensitivity to such issues as community attitudes.

The IRB will include both men and women as members; members of more than one profession; at least one member whose primary concerns are in nonscientific areas; and at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

If the IRB regularly reviews research that involves a vulnerable category of subjects, (such as children, pregnant women, prisoners, or the institutionalized mentally disabled), the IRB will include one or more individuals who are primarily concerned with the welfare of these subjects.

Each member of the IRB will have a designated alternate. Both members and alternates will serve staggered three-year terms. Both members and alternates are responsible for being informed on all IRB policies and procedures and the applicable laws and regulations. The IRB members are expected to review all the cases as well as to attend and to vote at the meetings of the IRB. The alternates are encouraged to review all the cases, to attend the meetings, and to participate in the discussions; but they may not vote unless their designated member is absent.

Members and alternates are appointed by the Vice Chancellor for Research after consultation with the Executive Secretary of the Institutional Review Board.

2. Operation of the IRB

The IRB meets regularly, normally at least monthly, to review proposed and continuing activities involving human subjects and to carry out its various responsibilities. A quorum is defined as a simple majority of the number of members of the IRB. For review of research governed by HHS regulations, the IRB quorum must include at least one member whose primary concerns are in nonscientific areas. No member or alternate shall be involved in either the initial or continuing review of activity in which he or she has a conflicting interest, except to provide information requested by the Board.

The Institutional Review Board will adopt a variety of mechanisms to assure depth and breadth of review, including the use of primary and secondary reviewers; a track system to group activities with similar levels of complexity; and a provision for inviting individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the IRB. In addition, the IRB may invite principal investigators to attend the Institutional Review Board meeting for first-hand discussion with the Board.

The Board will determine that the criteria for IRB approval are met and will recommend the frequency of continuing review and the nature and extent of any monitoring of the research or consent process to be required. See Part III, Tables 6A and 6B, pages 41-44.)

In order for work to be approved by the IRB, it shall receive the approval of a majority of those members present at the meeting.

The Board will provide for expedited review of certain categories of research which it will designate with due consideration of applicable regulations of sponsoring agencies. Under the expedited review procedure, IRB review will be carried out by specific IRB members assigned according to their expertise. The assigned reviewer will report his or her recommendation to the Executive Secretary. If the recommendation is for approval, the decision will be communicated immediately to the investigator and will be reported at the next IRB meeting. If the decision is for disapproval or a major change, the proposed research will be placed on the agenda for full IRB discussion.

For work governed by HHS regulations, expedited review will only be available for categories listed in the HHS regulations and for minor changes in previously approved research during the period of valid approval.

The Board will provide written notice to principal investigators of the disposition of their proposals. If the proposal is approved, the letter will include the period for which the approval is valid, the requirements for reporting any emergent problems involving human subjects, the requirement for prior review in changes in procedures, and any other special terms and conditions. If the Board stipulates changes or if it disapproves the proposal, the written notification will state the basis for this decision.

The IRB is responsible for the continuing review system described in Part III, Section G. The IRB may undertake site visits, interviews, or other methods for monitoring the conduct of research and consent processes.

The Board will maintain adequate documentation of all IRB activities, including minutes of the IRB meetings. These minutes will be kept in sufficient detail to show attendance at the meetings, actions taken by the IRB, the vote on the actions, the basis for requiring changes in or disapproval of research, and a written summary of the discussion of controverted issues and their resolution. Other records kept by the IRB are discussed in Part III, Section I.

B. IRB-Approved Departmental Review Bodies

A large number of activities involving human subjects at *no more than* minimal risk are undertaken each year *without external funding.* Some are part of introductory and research methods courses, some are short-term pilot projects, doctoral dissertations, and independent study projects. Some are regular faculty research projects. The large volume of such activities, the fact that subjects experience no more than the risks of ordinary life, and the fact that for many the time available for review is extremely short, all dictate that review must be expeditious and simple as well as responsible.

Departments with a significant number of such activities are encouraged to develop departmental guidelines on the basis of recurring types of minimal risk activities undertaken by the department and the well-established and accepted professional procedures used in the department. Such guidelines must comply with the UIUC policies, standards, and procedures. When such guidelines have been approved by the Institutional Review Board, the departmental review process may be used for non-exempt research involving human subjects which:

- are not externally funded,
- fall within the departmental guidelines, and
- place subjects at no more than minimal risk.

The departmental review body may refer any activity to the central IRB for review. When it receives proposals for research which do not fit within the departmental guidelines, it must refer the research to the central IRB. Furthermore, an investigator may appeal a departmental review body's disapproval to the Institutional Review Board.

Departments which elect to establish departmental review procedures must document the review and retain records sufficient to allow the IRB to review the department's experience with the decentralized review process. Such reviews will normally be undertaken annually and will involve an audit of a sample of cases reviewed at the departmental level.

Appendix I: Bibliography of Ethical Codes

The Declaration of Helsinki: Recommendations Guiding Doctors in Clinical Research, adopted by World Medical Association in 1964

American Medical Association
535 North Dearborn Street
Chicago, IL 60610

Professional Ethics: Statements and Procedures of the American Anthropological Association (September, 1973)

American Anthropological Association
1703 New Hampshire Avenue, NW
Washington, DC 20009

Patients' Bill of Rights (November 17, 1972)

American Hospital Association, Inc.
840 North Lake Shore Drive
Chicago, IL 60611

AMA: Principles of Medical Ethics including "Ethical Guidelines for Clinical Investigation" in *Current Opinions of the Judicial Council of the American Medical Association* (1981)

American Medical Association
535 North Dearborn Street
Chicago, IL 60610

Human Rights Guidelines for Nurses in Clinical and Other Research (1975)

American Nurses' Association, Inc.
2420 Pershing Road
Kansas City, MO 64108

Ethical Standards (1981)

American Personnel and Guidance Association
5203 Leesburg Pike
Falls Church, VA 22041

Ethical Principles in the Conduct of Research with Human Participants (copyright 1973)

American Psychological Association, Inc.
1200 Seventeenth Street, NW
Washington, DC 20036

Ethical Principles of Psychologists (1981 Revision)

American Psychological Association, Inc.
1200 Seventeenth Street, NW
Washington, DC 20036

Code of Ethics of American Sociological Association (September 1, 1971)

American Sociological Association
1722 N Street, NW
Washington, DC 20036

Code of Ethics of the National Association of Social Workers (1979)

National Association of Social Workers, Inc.
1425 H Street, NW, Suite 600
Washington, DC 20005

Ethical Standards for Research with Children
Society for Research in Child Development
University of Chicago Press
5801 Ellis Avenue
Chicago, IL 60637

Copies of these publications are available for review in the office of the Executive Secretary of the Institutional Review Board, Room 125 Coble Hall, and in the University Library. Copies may be obtained from the addresses given above.

Appendix II: Examples of Consent Forms

CONSENT FORM EXAMPLE Ia FOR A PROJECT AT MORE THAN MINIMAL RISK

Required Elements*

CONSENT TO PARTICIPATE IN RESEARCH

Identification of Project

"The Effects of Sleep Deprivation on Motor Control and Response Time Tasks"

Consent

I state that I am over eighteen years of age, in good physical health, and wish to participate in a program of research being conducted by Freda Smith of the UIUC Psychology Department.

Purpose

The purpose of the research is to measure the effects of prolonged sleep loss on motor control and response time tasks.

Procedures

The experimental procedures involve three sessions four weeks apart during which I will be asked to go without sleep for periods of 24 to 48 hours. I will not know the length of the sleepless period ahead of time. At various times during the sleepless period I will be asked to perform various simple tasks and to respond to sounds or lights by pushing a button.

I understand that there will be a responsible staff member present at all times after the first twelve hours. I understand that my blood pressure, respiration, and pulse rate will be checked during the experiment.

Risks and/or Discomforts

I understand that as a result of sleep loss I may experience extreme tiredness, feelings of disorientation, slight depression, irritability, and sleep disturbances over a short period of time. I understand that there are normally no long term effects associated with the periods of sleeplessness involved in this experiment.

Benefits

Opportunity to Ask Questions

Freedom to Withdraw

I understand that the experiment is not designed to help me personally, but that the investigator hopes to learn about the relationship between sleep loss and the ability to perform tasks like those needed for the safe operation of machinery and cars. I understand that I am free to ask questions or to withdraw from participation at any time.

In the event of physical injury resulting from participation in this study, I understand that immediate medical treatment is available at the McKinley Health Service. I also understand that the University of Illinois will not provide compensation for any injury sustained as the result of participation in this research except as required by law.

Name, Address, and Phone Number of Investigator

Freda Smith, Responsible Principal Investigator
Albert Nicholas, Research Assistant
415 Psychology Building, Phone: 333-0110

Signature of Subject

_____
Signature of Research Subject

Date

_____
Date

* The elements required for informed consent are listed to the left of the Consent Form itself to indicate the location of each element in this particular example. For research governed by the regulations of the U.S. Department of Health and Human Services or the Food and Drug Administration additional elements may be required; see Part II, Tables 1 and 2, pages 16-20.

CONSENT FORM
EXAMPLE Ib
SHORT FORM OF CONSENT FOR PROJECT AT MORE THAN MINIMAL RISK
WRITTEN SUMMARY OF WHAT IS PRESENTED ORALLY TO SUBJECTS (PART 1)

Required Elements*	
Identification of Project	"The Effects of Sleep Deprivation on Motor Control and Response Time Tasks" Subjects will be over eighteen years of age and in good physical health.
Purpose	The purpose of the research is to measure the effects of prolonged sleep loss on motor control and response time tasks.
Procedures	The experimental procedures involve three sessions, four weeks apart, during which subjects will be asked to go without sleep for periods of 24 to 48 hours. Subjects will not know the length of the sleepless period ahead of time. At various times during the sleepless period subjects will be asked to perform various simple tasks and to respond to sounds or lights by pushing a button. There will be a responsible staff member present at all times after the first twelve hours. Subjects' blood pressure, respiration, and pulse rate will be checked during the experiment.
Risks and/or Discomforts	As a result of sleep loss, subjects may experience extreme tiredness, feelings of disorientation, slight depression, irritability, and sleep disturbances over a short period of time. Normally no long-term effects result from the periods of sleeplessness involved in this experiment.
Benefits **Opportunity to Ask Questions** **Freedom to Withdraw**	The experiment is not designed to help subjects personally, but the investigator hopes to learn about the relationship between sleep loss and the ability to perform tasks like those needed for the safe operation of machinery and cars. Subjects are free to ask questions and to stop participating at any time. In the event of physical injury resulting from participation in this study, immediate medical treatment is available at the McKinley Health Service. The University of Illinois will not provide compensation for any injury sustained as the result of participation in this research except as required by law.
Signatures:	
Staff Member	Signature of Staff Member _____
Witness	Signature of Witness to Explanation _____
Date	Date _____
Name, Address, and Phone Number of Investigator	Freda Smith, Responsible Principal Investigator Albert Nicholas, Research Assistant 415 Psychology Building Phone: 333-0110

* The elements required for informed consent are listed to the left of the Consent Form itself to indicate the location of each element in this particular example. For research governed by the regulations of the U.S. Department of Health and Human Services or the Food and Drug Administration additional elements may be required; see Part II, Tables 1 and 2, pages 16-20.

CONSENT FORM
EXAMPLE I b
SHORT FORM OF WRITTEN CONSENT
(PART 2)

Required Elements*

Consent

Identification of Project

Explanation Has Been Provided

Opportunity to Ask Questions and Freedom to Withdraw

I state that I am over eighteen years of age, in good physical health, and agree to participate in a program of research being conducted by Professor Freda Smith of the UIUC Psychology Department entitled, "The Effects of Sleep Deprivation on Motor Control and Response Time Tasks." The purpose, procedures, risks, and benefits of this research have been explained to me and I have received a written summary of this explanation. I understand that I may ask questions and I am free to withdraw at any time.

In the event of physical injury resulting from participation in this study, I understand that immediate medical treatment is available at the McKinley Health Service. I also understand that the University of Illinois will not provide compensation for any injury sustained as the result of participation in this research except as required by law.

Signatures: **Staff**

Signature of Staff Member _____

Subject

Signature of Subject or Subject's Representative _____

Witness

Signature of Witness to Signature _____

Date

Date _____

* The elements required for informed consent are listed to the left of the Consent Form itself to indicate the location of each element in this particular example. For research governed by the regulations of the U.S. Department of Health and Human Services or the Food and Drug Administration additional elements may be required; see Part II, Tables 1 and 2, pages 16-20.

CONSENT FORM
EXAMPLE II
FOR A PROJECT AT MINIMAL RISK

Required Elements*

Identification of Project

CONSENT FOR BLOOD TO BE DRAWN FOR USE IN A RESEARCH PROJECT

I, state that I am over eighteen (18) years of age and agree to participate in a program of research being conducted by Professor Stephen Daedalus of the UIUC Entomology Department.

Purpose

Purpose of the Project:

To study the effect of fresh and dried human blood on the digestive system of scarabaeidae and microcentrum.

The experimental procedure for the human subject is to donate a total of 3 samples of 10 ml. of blood two weeks apart.

Procedures

The blood will be drawn by a certified medical technologist, nurse, or other suitably qualified person.

Risks and/or Discomforts

The personal discomforts involved are: slight pain during the drawing of blood and, in rare cases, development of what is commonly known as "black and blue mark" caused by minor seeping of blood around the puncture.

Benefits

I acknowledge that I have been told that this procedure is not intended to benefit my personal health but will provide material for certain studies of insects.

Freedom to Withdraw and Opportunity to Ask Questions

Consent

I acknowledge that Professor Daedalus has fully explained to me the discomforts involved and the need for the research, has informed me that I may withdraw from participation at any time, and has offered to answer any questions which I may ask about the procedures to be followed. I freely and voluntarily consent to take part in this research project.

Name, Address, and Phone Number of Investigator

Stephen Daedalus, Responsible Project Investigator
Entomology Department, UIUC
20 Morrill Hall
Phone: 333-6714

Signature of Subject

_____
Signature of subject

Date

_____
Date

* The elements required for informed consent are listed to the left of the Consent Form itself to indicate the location of each element in this particular example. For research governed by the regulations of the U.S. Department of Health and Human Services or the Food and Drug Administration additional elements may be required; see Part II, Tables 1 and 2, pages 16-20.

CONSENT FORM
EXAMPLE III
FOR RESEARCH AT MINIMAL RISK INVOLVING CHILDREN AS SUBJECTS

Required Elements*

Address of Investigator

College of Education
Department of Elementary Education
1310 South Sixth Street
Champaign, IL 61820

(217) 333-2245

September 2, 1983

Identification of Project

Dear Parent:

We would like to include your child, along with his or her classmates in a project to see if we can train 10 and 11 year old children in survey and map-making skills.

Procedures

If your child takes part in this project, he or she will get extra training in the math lab in the school. Your child will also visit the County Court House to look at land plats and surveys and work with maps in the library. The total time needed for all training should not be more than eight hours and will take place over several weeks in April and May. Each child will be asked to give positive agreement to be included in the study; only those students who want to take part will do so. Any student may stop taking part at any time. The information collected from your child during this study will be kept strictly confidential and will not become a part of his or her school record.

Freedom to Withdraw at Any Time

Please let us know on the bottom of this letter whether you do or do not want your child to participate in this project. Ask your child to bring the reply to his or her teacher or school principal. If you have any questions about this research, please do not hesiate to ask them either by mail or by telephone at the numbers listed below.

Opportunity for Parent to Ask Questions

Benefits
Purpose

We look forward to working with your child. We think that our research may help improve the map skills of grade school children. We also think that our research will show that some parts of trigonometry can be studied in earlier grades in math than teachers have thought.

Yours truly,

Name and Telephone Numbers of Investigators

L. Ericksen, Associate Professor
(217) 333-2250

A. Vespucci, Assistant Professor
(217) 333-8187

Consent
Name of Child

I do/ do not / want my child, _____, to participate in the study described above.
Name of Child

Parent Signature
Date

_____ Date

_____ Signature

* The elements required for informed consent are listed to the left of the Consent Form itself to indicate the location of each element in this particular example. For research governed by the regulations of the U.S. Department of Health and Human Services or the Food and Drug Administration additional elements may be required; see Part II, Tables 1 and 2, pages 16-20.

Appendix III: Form IRB-1

FORM IRB-1
(9/83)

IRB Office Use

Case No._____

Reviewers_____

UIUC IRB

INFORMATION FOR REVIEW OF RESEARCH INVOLVING HUMAN SUBJECTS

NOTE: All investigators using human subjects should be thoroughly familiar with the policies, definitions, instructions, and procedures described in the UIUC policy manual, *HANDBOOK FOR INVESTIGATORS: FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH* (September 1983). This booklet is available from the Executive Secretary, Institutional Review Board, Graduate College, 125 Coble Hall, phone 333-2670. Inquiries may be directed to the staff at this office.

For projects requiring IRB review, submit this form plus one copy of the proposal for the project to be undertaken to the Institutional Review Board, 125 Coble Hall. Please fill in the form as completely as possible; do not refer merely to pages in the proposal. Attach additional material to the IRB-1 form only after the space available for response to a given question has been used.

1. RESPONSIBLE PROJECT INVESTIGATOR: (qualified faculty or staff supervisor)
   Soc. Sec. No.:
   NAME OF INVESTIGATOR: (if different)
   Soc. Sec. No.:
   DEPARTMENT:

2. TITLE OF PROJECT:
   PROJECT DATES:

3. _____New Project _____Continuation _____Renewal _____Change in procedure for a previously approved project

4. FUNDING:
   A. Status
   _____Proposal in preparation
   _____Pending agency decision
   _____Funded
   _____Not externally funded
   B. Funding Agency
   C. Grant or Contract No.
   D. Name and address of additional agency official to be notified of IRB approval, if any:

E. If this particular project is to be undertaken as part of a training or institutional support program, provide the following information:

Title of program:_____

Name of program director:_____

5. TYPE OF INVESTIGATOR:
   _____Faculty _____Graduate student
   _____Staff _____Undergrad. student

6. TYPE OF PROJECT:
   _____Research _____Independent study
   _____Demonstration _____Other
   _____Class project

7. NUMBER OF SUBJECTS:
   Including individuals who serve as "controls"
   _____

8. TYPE OF SUBJECT: (Check all appropriate blanks in both A. and B.)

A.
_____Adult, non-student
_____UIUC student
_____Minor
_____Other (explain)

B.
_____Normal volunteer
_____In-patient
_____Out-patient
_____Mentally retarded
_____Mentally disabled
_____Individual with limited civil freedom
_____Pregnant women, fetuses

9. ____ ____ Subjects will receive payment or some compensation for participation. (See *HANDBOOK* pages 8 and 44.) If yes, state amount and form of payment.
yes no

10. ____ ____ Access to subjects will be gained through cooperating institutions. (See *HANDBOOK* page 8.) If yes, provide information specified in *HANDBOOK* pages 44 and 45 as attachment to this form.
yes no

11. ____ ____ This project involves investigators at another U of I campus or another institution. If yes, identify investigators and institutions.
yes no

12. ____ ____ Project involves use of drugs or medical devices not certified by FDA for clinical use for this purpose. (See *HANDBOOK* pages 24 and 45.)
yes no

13. ____ ____ Investigator has, or has applied for, Investigational New Drug certification by the FDA for the use of drugs included in this project. If yes, provide copy of FDA Form #1571.
yes no

14. ____ ____ Investigator has or has applied for an Investigational Device Exemption (IDE) from FDA for the use of a significant risk medical device in this project.
yes no

15. OBJECTIVES AND SIGNIFICANCE OF THE PROPOSED RESEARCH INVOLVING HUMAN SUBJECTS:

16. VOLUNTARY PARTICIPATION: Describe method (a) for selecting subjects and (b) for assuring that their participation is voluntary. If subjects are children and they are capable of assent, describe provisions for soliciting their assent as well as the provisions for soliciting permission of their parent(s) or authorized representative. (For requirements of consent and assent, see *HANDBOOK*, page 5 and pages following and 12 and pages following.)

A copy of the consent form to be signed by the subject (if applicable) and/or any explanation to be given to the subject should be attached to this form. If no consent form is to be used, explain the procedures to be used to assure that participation is voluntary. If any information is withheld from subjects, identify, justify the withholding, and describe debriefing plan if any. Special requirements for consent need to be met for certain subject populations See especially Table 1, page 16 and pages following.

17 **PROCEDURES:** Describe how subjects will be involved. (Attach additional page only if more space is needed.)

18. CONFIDENTIALITY OF DATA: If data are collected which could be associated with individual subjects, describe the methods to be used to ensure the confidentiality of data obtained. (See *HANDBOOK* pages 7, 21, and 42.) Confidentiality for data will be required unless subjects give express permission that their data may be identified.

19 RISKS: Will subjects in the proposed work be placed at *more than minimal risk* (as defined in *HANDBOOK* pages 21-24)?

_____Minimal risk _____More than minimal risk _____Uncertain

Describe the risks to the subject (whether or not you consider them to be risks of ordinary life) and precautions that will be taken to minimize them. The concept of risk goes beyond physical risk and includes risks to the subject's dignity and self-respect, as well as psychological, emotional, or behavioral risk.

20. BENEFITS: Describe the benefits to the subject and/or society. The IRB must have sufficient information to make a determination that the benefits outweigh whatever risks are involved. (See *HANDBOOK* pages 2, 3, 12, 16, 41, and 42.)

CERTIFICATIONS:

1. I am familiar with the *HANDBOOK FOR INVESTIGATORS* (September 1983). I will adhere to the policies and procedures explained therein.
2. Should changes in procedures involving human subjects become advisable, I will submit them for review *prior to* initiating the change.
3. If any problems involving human subjects occur, I will immediately notify the Departmental Executive Officer and the Executive Secretary of the Institutional Review Board.

Signatures: Date:_____

_____ _____

Responsible Project Investigator (RPI) Investigator, if different from RPI

FOR OPTIONAL DEPARTMENTAL USE:

The activity described herein is in conformity with IRB-approved departmental guidelines.

_____ _____

Departmental Executive Officer (or designee) Date

28—7-83—67144

Appendix IV: Requirements for Federally Funded[1] Research Involving Certain Subject Populations

A. SPECIAL REQUIREMENTS FOR FEDERALLY FUNDED RESEARCH INVOLVING CHILDREN

In addition to the requirements specified elsewhere in this handbook, the following requirements are imposed on all research involving children that is supported by or governed by HHS regulations.[2]

1. Consent

a. Assent of Children

i. The IRB shall determine that adequate provisions are made for soliciting the assent of children who are subjects in research, when, in the judgment of the IRB, the children are capable of providing assent.

In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol or for each child, as the IRB deems appropriate.

If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted *or* that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research.

Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirements under certain circumstances. (See Table 1, especially parts **A.(c)**, **(d)**, and **(f)**, **B.(a.3)** and **(b)**.)

ii. For research involving children capable of assent, the IRB will require the investigator to propose what the child will be told about the research, how the information will be presented to him or her, and how assent will be obtained. The information presented to the child will vary from a simple description of what the child will experience to the equivalent of the information that would be presented to an adult subject. Younger and less sophisticated children will be given simple information on what they will experience as they participate in the

[1] Most federal sponsors of research require compliance with HHS regulations for the protection of human subjects in research.

[2] HHS Regulations on "Children Involved as Subjects in Research: Additional Protections" was published in the *Federal Register,* vol. 48, no. 46, March 8, 1983, pages 9814-9819.

research. For older and more sophisticated children, more detailed information will be given together with a statement about the fact that the project is for the purpose of research. *All* children must be informed that they are free to withdraw from participation at any time.

The IRB will review and approve methods for assuring assent and base its decisions on the premise that, like maturity, a child's understanding is a gradually expanding developmental process which cannot be stated in terms of chronological age, as well as on the principle that the autonomy of all persons should be respected.

b. Permission of Parents or Guardian

i. When children are subjects in research, the IRB shall determine, in accordance with and to the extent that consent is required by UIUC policy stated in Part II, Section **D.1.** (pages 12-20), that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that the permission of **one parent** is sufficient for research to be conducted where:

- the research does not involve greater than minimal risk,
- the research involves greater than minimal risk, but presents the prospect of direct benefit to the individual subjects.

ii. When children are included in:

- research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subjects' disorder or condition *or*
- research not otherwise approvable that presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health of children and permission is to be obtained from parents then **both parents** must give their permission *unless* one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

c. Consent May Be Waived

Under several circumstances, the IRB may waive some or all of the consent requirements. The waiver conditions for all types of research projects are described in Table 1, Part **A.**(c), (**d**), and (f) and Part **B.**(a) and (**b**). In addition, the IRB may waive consent of the parents or guardian if the IRB determines that:

i. a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), *and*

ii. the waiver is not inconsistent with federal, state, or local laws, *and*

iii. an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol; the risk and anticipated benefit to the research subjects; and their age, status, and condition.

d. Documentation of Informed Consent and Assent

When children are included as subjects in research, permission by parents or guardians shall be documented in accordance with and to the extent required by *a.* through *c.* above. When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

2. Criteria for Approval by the IRB

a. Research involving not greater than minimal risk

When children are included in research involving *not greater than minimal risk,* the IRB must find that adequate provisions are made for soliciting the assent of children and the permission of their parents.

b. Research involving more than minimal risk, but presenting the prospect of direct benefit to individual subjects

When children are included in research in which the IRB finds that *more than minimal risk* is presented by an intervention or procedure that holds out the prospect of direct benefit to the individual subject or by a monitoring procedure that is likely to contribute to the subject's well-being, the IRB must find that:

i. the risk is justified by the anticipated benefit to the subjects, *and*

ii. the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches, *and*

iii. adequate provisions are made for soliciting the assent of children and permission of their parents and guardians.

c. Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subjects' disorder or condition

Where children are included in research in which more than minimal risk to children is presented by an intervention or procedure that *does not* hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is *not* likely to contribute to the well-being of the subjects, the IRB must find that:

i. the risk represents a minor increase over minimal risk, *and*

ii. the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations, *and*

iii. the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition, *and*

iv. adequate provisions are made for soliciting assent of the children and permission of their parents or guardians.

d. Research not otherwise approvable

Where children are included in plans for research not otherwise approvable,

i. the IRB must find that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children, *and*

ii. the Secretary of Health and Human Services, after consultation with a panel of experts in pertinent disciplines (e.g., science, medicine, education, ethics, law) and following an opportunity for public review and comment, has determined that the research is, in fact, approvable by the IRB or that:

- the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; *and*
- the research will be conducted in accordance with sound ethical principles; *and*
- adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians.

e. When children who are wards of the state are involved as subjects in research

i. The requirements for children who are wards of the state or any other agency, institution, or entity do not differ from those for other children if the research:

a. involves no more than minimal risk or

b. involves greater than minimal risk, but presents the prospect of direct benefit to the individual subjects.

ii. Children who are wards of the state or any other agency, institution, or entity can be included in research described in Section **2.**, *c.* or *d.* above only if the research is:

a. related to their status as wards; or

b. conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are *not* wards.

iii. If the research is approved under Section **2.***e.ii.* (immediately above), the IRB will require appointment of an advocate for each child who is a ward in addition to any other individual acting on behalf of the child as guardian or *in loco parentis.*

3. Exemptions

When children are involved as subjects in research regulated by HHS, the kinds of research that are exempted from prior review are more limited than when children are not involved. Note the following:

Exemption 3: The exemption from prior review of research involving survey or interview procedures does not apply to research involving children. Such projects must be submitted to the IRB for review. (See page 29.)

Exemption 4: The exemption from prior review of research involving observation of public behavior applies to research involving children *only* if the investigator(s) does not participate in the activity being observed. (See page 30.)

B. SPECIAL REQUIREMENTS FOR FEDERALLY FUNDED RESEARCH INVOLVING PRISONERS AS SUBJECTS

In addition to the requirements specified elsewhere in this handbook, the following requirements are imposed on all research involving prisoners that is supported by or governed by HHS regulations.

1. General Limitations

The *only* types of research involving prisoners which may be approved by the IRB are the following:

a. Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

b. Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

c. Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary of Health and Human Services has consulted with appropriate experts, including experts in penology, medicine, and ethics and published notice in the *Federal Register* of his or her intent to approve such research; *or*

d. Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups that may not benefit from the research, the study may proceed only after the Secretary of Health and Human Services has consulted with appropriate experts, including experts in penology, medicine, and ethics and published notice in the *Federal Register* of his or her intent to approve such research.

2. Criteria for Approval by the IRB

In addition to applying other criteria for approval (Tables 6A and 6B), the IRB shall make the following determinations:

a. Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities, and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired.

b. The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers.

c. Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the IRB justification in writing for following some other procedures, control subjects must

be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project.

d. The information is presented in language that is understandable to the subject population.

e. Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; *and*

f. Where the IRB finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences and for informing participants of this fact.

3. Exemptions

All research governed by HHS regulations involving prisoners must be reviewed by the IRB. No research governed by HHS regulations that involves prisoners as subjects is exempt from prior review by the IRB.

C. SPECIAL REQUIREMENTS FOR FEDERALLY FUNDED RESEARCH INVOLVING FETUSES, PREGNANT WOMEN, AND HUMAN *IN VITRO* FERTILIZATION*

In addition to the requirements specified elsewhere in this handbook, the following requirements are imposed on all research involving fetuses, pregnant women, and human *in vitro* fertilization.

1. General Limitations

The only conditions under which research involving fetuses, pregnant women, and human *in vitro* fertilization are permitted are the following:

a. appropriate studies on animals and nonpregnant individuals have been completed;

b. except where the purpose of the research is to meet the health needs of the mother of the particular fetus, the risk to the fetus is minimal and, in all cases, is the least possible risk for achieving the objectives of the research;

c. individuals engaged in the research will have no part in: (i) any decisions as to the timing, method, and procedures used to terminate the pregnancy and (ii) determining the viability of the fetus at the termination of the pregnancy;

d. no procedural changes that may cause greater than minimal risk to the fetus or the pregnant woman will be introduced into the procedure for terminating the pregnancy solely in the interest of the research; *and*

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* The full text of the HHS regulations concerning research involving pregnant women, fetuses, and human *in vitro* fertilization can be found in the *Federal Register* as follows: 40 FR 33528, August 8, 1975 as amended at 40 FR 51638, November 6, 1975; 43 FR 1758, January 11, 1978; 43 FR 51559, November 3, 1978.

e. no inducements, monetary or otherwise, may be offered to terminate the pregnancy for purposes of the research.

2. Additional Criteria for IRB Approval

In addition to applying the other criteria for approval (Tables 6A and 6B, pages 41 and 42), the IRB will determine the following:

a. For research *directed toward* pregnant women as subjects

i. No pregnant woman may be involved as a subject in research unless:

- the purpose of the research is to meet the health needs of the mother, and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, *or*
- the risk to the fetus is minimal.

ii. Research permitted under paragraph *a.* of this section may be conducted only if the mother and father are legally competent and have given their informed consent after having been fully informed regarding the possible impact on the fetus, except that the father's informed consent need not be secured if:

- the purpose of the research is to meet the health needs of the mother, *or*
- his identity or whereabouts cannot reasonably be ascertained, *or*
- he is not reasonably available, *or*
- the pregnancy resulted from rape.

b. For research directed toward fetuses *in utero* as subjects

i. No fetus *in utero* may be involved as a subject in any research unless:

- the purpose of the research is to meet the health needs of the particular fetus and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, *or*
- the risk to the fetus imposed by the research is minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means.

ii. Such research may be conducted only if the mother and father are legally competent and have given their informed consent, except that the father's consent need not be secured if:

- his identity or whereabouts cannot reasonably be ascertained, *or*
- he is not reasonably available, *or*
- the pregnancy resulted from rape.

c. Research directed toward fetuses *ex utero,* including nonviable fetuses, as subjects

i. Until it has been ascertained whether or not a fetus *ex utero* is viable, a fetus *ex utero* may not be involved as a subject in research unless:

- there will be no added risk to the fetus resulting from the research and the purpose of the activity is the development of important biomedical knowledge that cannot be obtained by other means, *or*
- the purpose of the research is to enhance the possibility of survival of the particular fetus to the point of viability.

ii. No nonviable fetus may be involved as a subject in research unless:

- vital functions of the fetus will not be artificially maintained,
- experimental research, which of itself would terminate the heartbeat or respiration of the fetus, will not be employed, *and*
- the purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means.

iii. In the event the fetus *ex utero* is found to be viable, it may be included as a subject in the research only to the extent permitted by the other requirements listed above.

iv. Such research may be conducted only if the mother and father are legally competent and have given their informed consent, except that the father's informed consent need not be secured if:

- his identity or whereabouts cannot reasonably be ascertained, *or*
- he is not reasonably available, *or*
- the pregnancy resulted from rape.

d. For research involving the dead fetus, fetal material, or the placenta

Activities involving the dead fetus; mascerated fetal material; or cells, tissue, or organs excised from a dead fetus shall be conducted only in accordance with any applicable state or local laws regarding such research.

3. Modification or Waiver of Specific Requirements

Upon the request of an applicant (with the approval of the Institutional Review Board), the Secretary of Health and Human Services may modify or waive specific requirements listed above with the approval of the Ethical Advisory Board after such opportunity for public comment as the Ethical Advisory Board considers appropriate in the particular instance. In making such decisions, the Secretary will consider whether the risks to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant such modification or waiver and that such benefits cannot be gained except through a modification or waiver. Any such modifications or waivers will be published as notices in the *Federal Register.*

4. Exemptions

No research governed by HHS regulations directed toward pregnant women or fetuses is exempt from prior review by the IRB.

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